EXHIBIT 8

CARR ENGINEERING, INC.
12500 CASTLEBRIDGE DRIVE HOUSTON, TEXAS 77065-4532
TELEPHONE 281-894-8955

April 23, 2021

Mr. John Duffy
SWANSON, MARTIN & BELL, LLP
330 North Wabash, Suite 3300
Chicago, IL 60611

Re: In re Pacific Fertility Center

Dear Mr. Duffy,

Carr Engineering, Inc. (CEI) and I have been retained by attorneys representing Chart Inc. entities in the matter referenced above to investigate and analyze the Chart MVE - 808 cryogenic freezer TEC 3000 control system involved in the incident of March 4, 2018 at Pacific Fertility Center (PFC) in San Francisco, California. Specifically, I have focused on the control design, failsafe design, and performance of the TEC 3000 freezer controller as they relate to allegations raised in this matter.

Summary of Opinions

In the course of my investigation, I have been provided with and have considered materials listed in Attachment A and reviewed or generated materials listed in Attachment B. Based upon the materials reviewed and my investigation to date, the details of which are found in this report, I have reached the following opinions to a reasonable degree of engineering certainty:

1. The TEC 3000 controller design provides control functions and failsafe functions to support the operation of the Chart MVE 808 liquid nitrogen (LN2) cryogenic freezer. The design is commonplace and consistent with peer cryogenic freezer controls. The TEC 3000 is not unreasonably dangerous in its design and manufacturing.

2. The subject PFC Tank 4 TEC 3000 controller demonstrated both control and failsafe functionality prior to events with the controller which occurred on February 15, 2018.

3. Changes in LN2 usage level calculations from the subject TEC 3000 controller leading up to events occurring on February 15, 2018 were not displayed.

4. The subject PFC Tank 4 TEC 3000 controller continued to demonstrate failsafe functionality during the time from events on February 15, 2018 thru the time of the tank failure incident reported on March 4, 2018 and beyond.

5. PFC personnel did not notify Chart immediately after the incident on February 15, 2018 resulting in the subject TEC 3000 controller entering a constant state of alarm. Chart would have proceeded with troubleshooting recommendations and service or return procedures if notified by PFC promptly.

6. The manual monitoring method employed by PFC before and after the event with the subject controller on February 15, 2018 was insufficient to accurately monitor and record LN2 usage levels during this period of operation.

Supporting details and bases for each of these opinions can be found in the paragraphs that follow.

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1. Experience and Qualifications to Render Opinions

I am a resident of the State of Texas and an employee of Carr Engineering, Inc., a Texas corporation at 12500 Castlebridge Drive, Houston, Texas 77065. I received my bachelor's degree in Electrical Engineering and a master's degree in Electrical Engineering with emphasis in Control Systems from The Ohio State University in Columbus, Ohio in 1987 and 1991 respectively. I have compiled over 30 years of automotive engineering experience including collegiate co-op assignments prior to 1987 combined with professional employment from 1987 until the present. Over the course of my professional career, I have been involved with areas of algorithm development, software architecture design, countermeasure and diagnostic design, functional safety development, and system engineering requirements management emphasizing controlled brake and controlled suspension products.

From 1987 until 2004, I held several Algorithm Development and System Engineer roles for the Delco Products division of General Motors. This same division later became Delphi Chassis. In these roles I was responsible for the specification, design, evaluation, and testing of multiple vehicle systems including safety, handling, and braking systems, with various levels of integrations with powertrain (engine/transmission) systems and steering systems. During these assignments I gained state-of-the-art experience with electronic sensor processing, diagnostic and countermeasure implementation, serial communications, and control algorithms.From 2004 until 2016, I held two Engineering Manager positions with Delphi Chassis (later becoming BWI Group, Inc.). The first position I held, from 2004 to 2008, was Manager of the Diagnostics and Communications group. In this role I was responsible for providing technical direction regarding diagnostic algorithms, countermeasure design, serial diagnostic communication protocols, and bootloader flashing methods for core products. My second managerial position, from 2008 to 2016, was that of Manager of the Systems and Software Group. In this capacity, I provided technical direction to the software teams responsible for software implementation within controlled brake products (anti-lock brakes, traction control, and stability control). The software teams under my leadership spanned global locations including Brighton, Michigan; Shanghai, China; and Bangalore, India.

An expertise that I have developed during my industry tenure from various assignments is design and implementation of control system failsafe and diagnostics. Failsafe and diagnostic design provides methods and measures to mitigate risks given an abnormal system operating condition. Towards this objective, I have designed, implemented, reviewed and approved failsafe and diagnostic designs at the sensor, electronic controller, software operation system, and automotive vehicle levels during my career.

Over the last 10 years, I have developed particular expertise in the areas of functional safety design and the management processes for systems engineering requirements. Since 2008, I have been a member of the U.S. Technical Advisory Group responsible for the development of the ISO-26262 functional safety standard for road vehicles. Managing the development of production embedded software for Delphi's safety systems also required me to become well versed in industry methods such as ASPICE (Automotive Software Process Improvement and Capability dEtermination) along with various disciplines of systems engineering to effectively specify, communicate, implement, and verify requirements.

Since February 2016, I have been employed as a Principal Engineer at Carr Engineering, Inc. In this role, I rely on my 30+ years of industry experience to perform investigations to determine the causes, conditions, and circumstances of defect allegations related to all forms of embedded system design, not just those specifically found in automotive microprocessors. Regardless of the application, I am able to analyze claims pertaining to embedded system design, countermeasure strategy, software implementation, and fault analysis. In the automotive context, this includes emerging technologies such as advanced driver assistance system (ADAS) features, autonomous driving technologies and their derivatives, and cybersecurity matters.

Throughout my professional career I have published and presented material related to my work as an engineer. This effort began in 1991 with my master's thesis, "A DSP Hybrid Simulator For Evaluating Anti-Lock Brake System Control Design" and has continued to the present. I have authored and co-authored several SAE papers in my area of expertise and have been invited to present at several technical conferences focusing in the areas of functional safety and software development. In addition to publishing and presentation, I have been awarded several U.S. Patents in these same areas, and have been the recipient of two GM Boss Kettering Awards: Automotive Chassis Control – Integrated Chassis (1996) and Unified Brake and Suspension Control (2000).

Carr Engineering, Inc. charges $395 per hour for my services. Copies of my current CV and testimony list can be found as Attachments C and D respectively.

2. Plaintiff Complaint and Allegations

I have reviewed the 3rd Amended Complaint filed by the Plaintiffs in this matter relating to the incident at PFC on March 4, 2018. In the complaint, the Plaintiffs allege that the TEC 3000 controller "malfunctioned shortly before the incident" and that "To the extent this malfunctioning controller contributed to the harm suffered by Plaintiffs, Chart is responsible for that as well."

Plaintiffs allege that Chart was negligent because "Chart should have recalled or retrofitted all tanks equipped with a TEC 3000 electronic control system prior to March 4, 2018." For support, Plaintiffs allege that the TEC 3000 controller "was prone to malfunction, leading to inaccurate measurements and false alarms" and that Chart knew or it was reasonably foreseeable that "customers would continue to use their cryogenic freezers without a fully functional controller."

I have considered these and other related allegations in my investigation of the TEC 3000 controller. I disagree that anything Chart did, or did not do, involving the TEC 3000 controller was negligent. The TEC 3000 controller was not dangerous or likely to be dangerous when used in a reasonable manner.

3. Incident Overview

I have reviewed materials received which provide an account of the incident at the Pacific Fertility Center. The PFC response to the College of American Pathologists (CAP) report [MSO001982 – MSO001991] states that PFC staff became aware of a loss of LN2 and failure of the Tank 4 system on Sunday March 4, 2018, approximately 12:30 p.m., during a routine check of the storage tank. PFC staff immediately took action to first replenish the LN2 in the failing tank, and then prepare the facility's backup tank for sample transfer.

Further in this report, it is acknowledged that preceding the incident of March 4, on February 15, 2018, the (TEC 3000 attached to Tank 4) controller generated erroneous and inaccurate "Low LN2" alarms and because of these alarms the controller was used only for daily temperature verification and LN2 filling as part of the laboratory shutdown process.

Subject PFC Tank 4 during post incident inspection.

The day following the incident of March 4, 2018, Tank 4 was observed to have experienced "serious deformation" of the upper inner wall of the tank as shown in the photo above. Subsequent to the PFC incident on March 4, 2018, it was confirmed by PFC staff that certain human tissue samples residing in Tank 4 had been adversely impacted.

4. Testimony Statements

To understand the Chart MVE-808 freezer development, operation, and distribution I have reviewed more than 43 depositions from Chart, Extron and PFC employees, PFC clients and investigating experts. I have referenced depositions statements below from PFC staff Dr. John Conaghan and Ms. Gina Cirimele to provide insight on how the MVE-808 freezer and TEC 3000 controller were used at PFC leading up to events of February 15 and March 4, 2018.

4.1 Dr. Joseph Conaghan

Dr. Joseph Conaghan, PFC Lab Director, was deposed on August 31, 2020. In his deposition Dr. Conaghan acknowledged "…a normal controller is capable of measuring the level of liquid inside the tank, and the controller is also capable of calculating usage of nitrogen inside the tank." However, when asked how often he would check the liquid nitrogen usage rate of Tank 4 leading up to the incident, he responded, "We didn't check usage."

Regarding the operation of the subject TEC 3000 controller prior to the March 4 incident, Dr. Conaghan stated that "…it stopped working on February 15th." When asked to further explain "it stopped working," Dr. Conaghan replied, "It lost its ability to measure the level of liquid nitrogen inside the tank. …Normally on the controller display, it tells you how much liquid is in the tank in inches. …When this controller failed, it was reading the level abnormally low, like 1 to 2 inches, like alarmingly low. And then, eventually it was reading 0."

Dr. Conaghan described the TEC 3000 alarm function in the following manner, "As soon as the controller lost its ability to measure the level of nitrogen in the tank, it immediately went into an alarm state." Further he stated, "We determined – I determined that the reason that the alarm was going off was because the controller thought there was no nitrogen in the tank."

When asked "Did you make a decision as to whether to keep the alarm operational or not?" Dr. Conaghan responded "My decision was to turn off the controller because it was in a constant state of alarm."

From the period from February 15, 2018 through March 4,2018, Dr. Conaghan described the Tank 4 monitoring process by stating, "In the absence of a normally functioning controller, we went to doing manual monitoring of the tank. …At the end of the day, the tank was topped up just as before, and the measurement of the liquid level in the tank was made using a dipstick. And the level was recorded."

4.2 Ms. Gina Cirimele

Ms. Gina Cirimele, PFC Embryologist, was deposed on August 31, 2020. In her deposition Ms. Cirimele described the normal measurement process on Tank 4 by stating, "We would read the level of the liquid nitrogen from the controller. …We would record it in our QC log." Further Ms. Cirimele determined the need to fill the freezer with LN2 by noting, "The level on the controller would be lower, at a lower range." Ms. Cirimele confirmed that she would record the liquid nitrogen level after completing the fill cycle. When asked where the LN2 measurements were recorded Ms. Cirimele responded, "We record the(m) manually in a

logbook". She confirmed that now the process is to input measurements into the Reflections program.

Ms. Cirimele acknowledged when asked "Has anyone ever forgotten to enter data at Pacific Fertility and then had to go back and put it in?" …"Yes, So if a value was not entered at the end of the day we would go back and look at our hard copy paper log and fill it in from that. So it was written down especially in that period of time of doing recording when you were first starting Reflections, some values would be forgotten to be put in. So we would go back and enter in the forgotten value or the missed value for the day."

When asked "In any of your jobs, have you ever been trained how to calculate liquid nitrogen consumption?" Ms. Cirimele responded, "Not before the incident." When asked to describe the LN2 fill point after the controller stopped working properly in February of 2018, Ms. Cirimele responded "We have a range that we would use. It wasn't the specific point that the controller had."

Ms. Cirimele confirmed that the Tank 4 controller was connected to a Sensaphone device and that the Sensaphone would call a cell phone and issue a text if an alarm condition was observed.

Work Performed and Analyses

5.1 MVE 808 – TEC 3000 system design

I have reviewed materials pertaining to the TEC 3000 controller system design. The TEC 3000 controller is an electronic embedded system controller designed for cryogenic freezer application such as the MVE 808 freezer model. The TEC 3000 system is designed to measure LN2 temperature and level measurements as inputs, provide solenoid output control to facilitate LN2 fill requirements, and features a configurable user interface providing visual and audible feedback for measurements, status and alarms. Capacity to record measurements, event and alarm status codes up to 30,000 time entries is also provided through non-volatile memory.

The TEC 3000 control design provides mechanisms to perform open loop manual control, semi-automated control, and closed loop automated control of the solenoids responsible for managing flow of LN2 to the tank. A plumbing assembly comprised of fill, bypass and purge solenoids is interfaced between the LN2 tank supply and the LN2 supply lines of the MVE 808 freezer. The manual mode is implemented by a momentary on / off switch mounted on the rear of the TEC 3000 controller. This switch controls the pair of fill solenoids contained within the MVE 808 plumbing assembly. The semi-automated control mode is controlled with the "START FILL" and "STOP FILL" buttons on the front of the TEC 3000 controller panel. The semi-automated mode sequences the purge, bypass and fill solenoids per specified requirements to facilitate the LN2 fill operation. The sequence commences with a start command and terminates with a stop command.

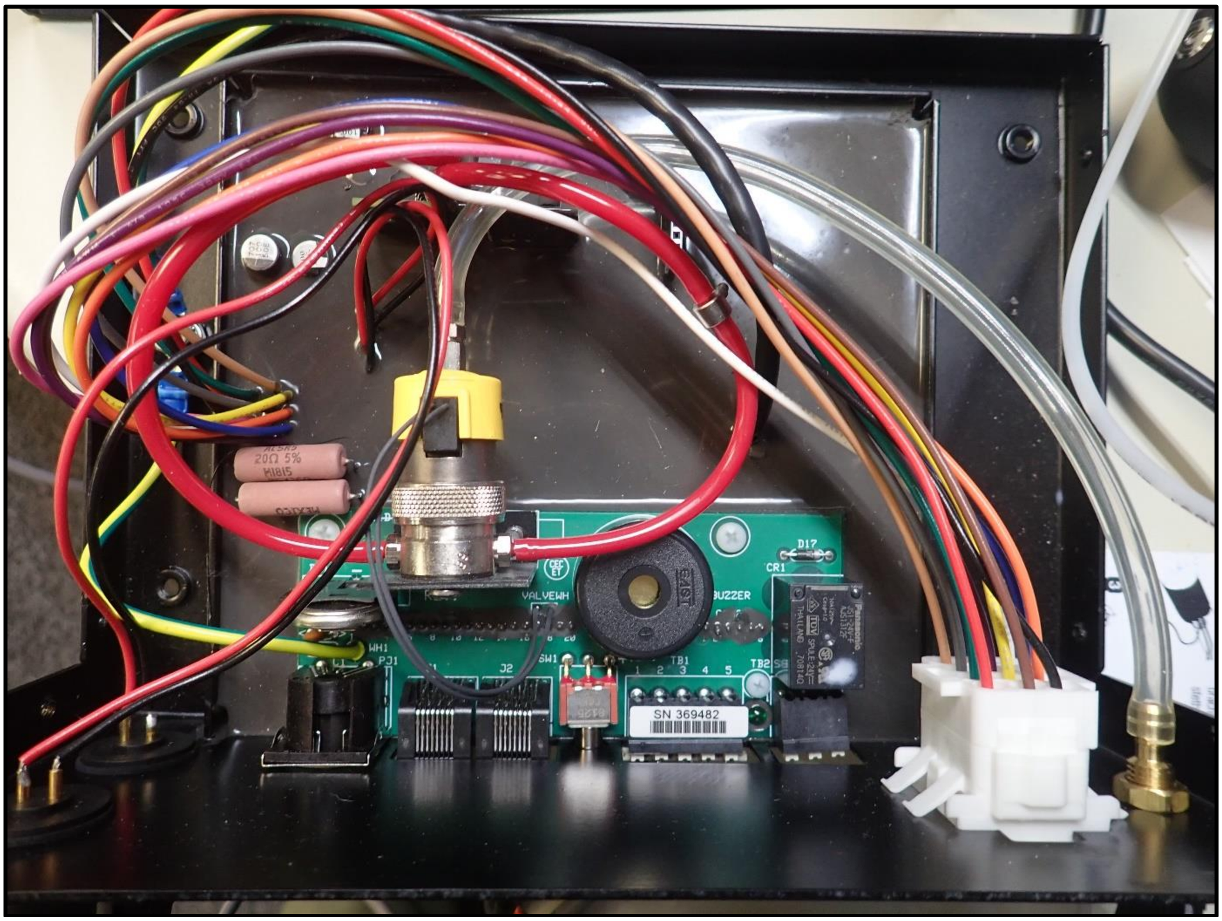
The automated control mode manages the fill operation utilizing feedback from LN2 level measurement and High and Low Level Setpoint parameters. A control strategy is implemented to sequence the solenoids to fill the freezer with LN2 until the High Level Setpoint level is reached, which turns the solenoids off. The solenoids are re-energized or turned on once the LN2 level falls below the Low Level Setpoint. Failsafe design is integrated with this control mode such that if the automated fill operation runs the solenoids beyond a time limit, the fill operation will be aborted. The time limit is a configurable parameter. This closed loop control mode is referred to as the "Auto Fill" feature within TEC 3000 controller documentation and setup menus.

Exemplar TEC 3000 controller shown performing Fill operation per display output.

The TEC 3000 control design also provides a mechanism to monitor the rate at which LN2 is consumed. Through normal usage and time, the LN2 will evaporate, reducing the amount of refrigerant in the freezer. The rate at which the LN2 evaporates for a given operating scenario can be established and serve as an indicator for normal operation. Usage rates in excess of this level may signify a pending issue relative to the LN2 supply.

The TEC 3000 controller can be configured to calculate and display this usage rate in inches or millimeters per day on the front display. The usage rate parameter displayed is an averaged or filtered value of the time required for the LN2 level to decrease 0.5 inches (12.7mm) extrapolated to a 24 hour period. This usage parameter is logged as part of the event log over time. This parameter is integrated with the failsafe design such that a Usage Warning will be issued if the LN2 usage rate doubles within a 24 hour period. A Usage Alarm will be issued if the LN2 usage rate increases by a factor of five within a 24 hour period.

I have been able to identify electronic components and circuit design features from a review of the TEC 3000 electronic schematic provided with discovery materials [CHART00061 – CHART00126] and an examination of TEC 3000 internal circuitry from an exemplar unit. The embedded (software/hardware) processing is provided by a PIC 18F8722 microcontroller. This device executes the software design with hardware interfaces for reading analog inputs and controlling outputs including the user display, solenoids, alarm signals and serial data exchange. The solenoid drive interfaces include reverse protection diodes against back electromotive force (EMF) possible from switching solenoid loads. The circuit responsible for LN2 level measurement includes an MPX100P pressure transducer device with capacity to measure 0 – 1.45 psi and convert to proportional voltage signal. Much of the main circuit board is encased in potting material to provide environmental protection for the components.



Internal components of exemplar TEC 3000 controller.

5.2 MVE 808 – TEC 3000 system safety design

I have reviewed materials pertaining to the TEC 3000 controller safety or failsafe design. Failsafe is an engineering term which describes the design specified to maintain safety for a system, and in the event of a failure, causes the system to revert to a state that will mitigate a potential hazard. Discovery documentation [CHART001432] indicates that the TEC 3000 control system was developed per industry methods to consider safe operation of the product. Two industry methods used in the development of the MVE 808 – TEC 3000 control system were the Design Failure Mode and Effects Criticality Analysis (DFMECA) and a Usability Risk Analysis. Both methods are intended to evaluate the product design and components, identify potential failure or product misuse, effects of the failure or misuse, risks of the effects specific to the user or in the case of a cryogenic freezer, freezer contents, and specify countermeasures to mitigate the risk. Examples of countermeasures implemented to mitigate risk within the TEC 3000 control include a battery backup system to enable continued operation given loss of AC power and alarms to indicate improper sensor connection.

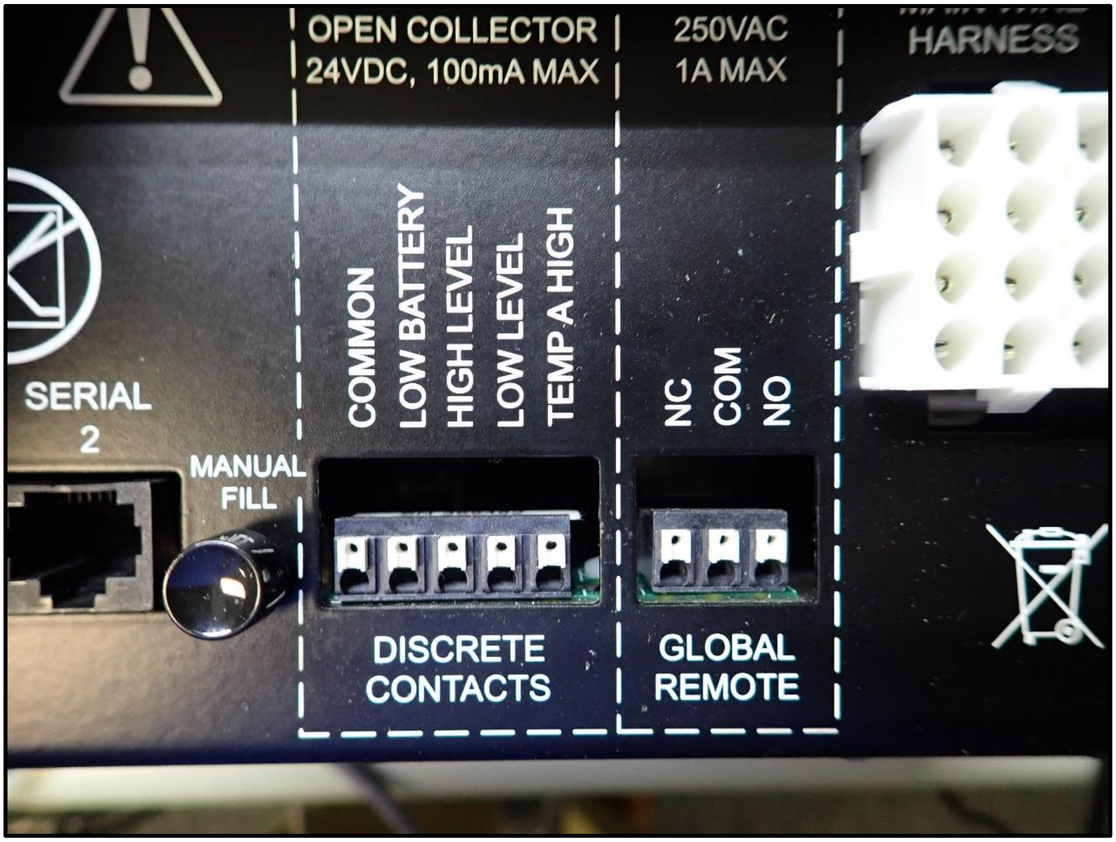
The MVE 808 – TEC 3000 DFMECA has been conducted by Chart Inc. to assess the entire cryogenic freezer system. System components are analyzed for potential failure modes, and their potential system effects ranked with respect to criticality. The components analyzed for the MVE 808 – TEC 3000 DFMECA include Battery Backup, Power Supply, Controller, Dewar, Plumbing Assembly, Cabinet, Bulk System and System Software.

An outcome from the safety development methods applied to the MVE 808 – TEC 3000 failsafe system design is the capacity for the TEC 3000 controller to alarm in the event of fault conditions which have the potential to result in a hazard or mishap and log their occurrence. Alarms are used as a component of the failsafe design to alert the system user to events or conditions of concern within the controlled process. In response to an alarm, the system user has a responsibility to acknowledge the alarm and determine corrective action if necessary. This action can range from simply clearing the alarm to understanding the plausibility of the alarm and the underlying conditions that led to it. Alarms may signify a specific condition or be symptomatic of a related issue. The TEC 3000 controller has capacity to alarm and report 18 fault conditions and 7 status events through combinations of audible, visual, and logged or recorded feedback. The table below summarizes the set of alarms and event codes embedded in the MVE 808 -TEC 3000 controller failsafe design.

TEC 3000 ALARM AND EVENT CODES			
AM	Alarm Mute	F	Filling
AH	Temp A High Alarm	FD	Fill Disabled
AL	Temp A Low Alarm	FT	Fill Time Alarm
BB	Running on Battery Power	HG	Hot Gas Bypass Time Alarm
BH	Temp A High Alarm	LH	High Level Alarm
BL	Temp A Low Alarm	LL	Low Level Alarm
BP	Bypass Sensor Open	LO	Lid Open Alarm
BV	Low Battery Voltage Low	PF	Power Failure
BY	Hot Gas Bypassing	SC	Stuck Closed Alarm
CA	Temp A Calibration Alarm	SO	Stuck Open Alarm
CB	Temp B Calibration Alarm	US	Liquid Usage Alarm
CG	Bypass Sensor Calibration Alarm	UW	Usage Warning
ZO - Level Zeroing			

TEC 3000 alarm and event code summary table with alarms shown in red and events shown in black.

The TEC 3000 design includes hardware outputs to interface with external monitoring systems such as the Sensaphone monitoring system.



Rear of TEC 3000 controller unit showing hardware ports for external monitoring interface.

5.3 Peer cryogenic freezer controller designs

I have performed a survey of materials related to cryogenic freezer controller peers of the Chart MVE 808 - TEC 3000 controller system. The objective of this survey was to assess whether the TEC 3000 controller design is commonplace and consistent with peer designs. I obtained public domain materials on controller designs from four manufacturers: ThermoFisher Scientific, CryoLogic, Lakeshore Cryotronics and Planer. A minimum of eleven product models were included, as some product references covered a range or series of individual products.

The products surveyed were comprised of two types of controllers: temperature controllers and temperature/LN2 level controllers for freezer applications. The temperature-only controllers have the capacity to monitor temperature compared to a setpoint and regulate temperature; some models include heating capability. The combination temperature and LN2 level controller designs have the capacity to monitor temperature and regulate a LN2 supply source. All models reviewed incorporate alarms to indicate if temperature is above or below a setpoint. All of the ThermoFisher Scientific models have alarms beyond temperature monitoring comparable to the Chart MVE 808 - TEC 3000 controller design. In particular, the controller for the ThermoFisher Cryoextra CE8100 model is nearly identical in appearance and functional description to the TEC 3000 controller model.

The table below summarizes findings of the peer cryogenic freezer controller design survey. Based on these results, I find the TEC 3000 controller model to be commonplace and consistent with peer cryogenic freezer controls.

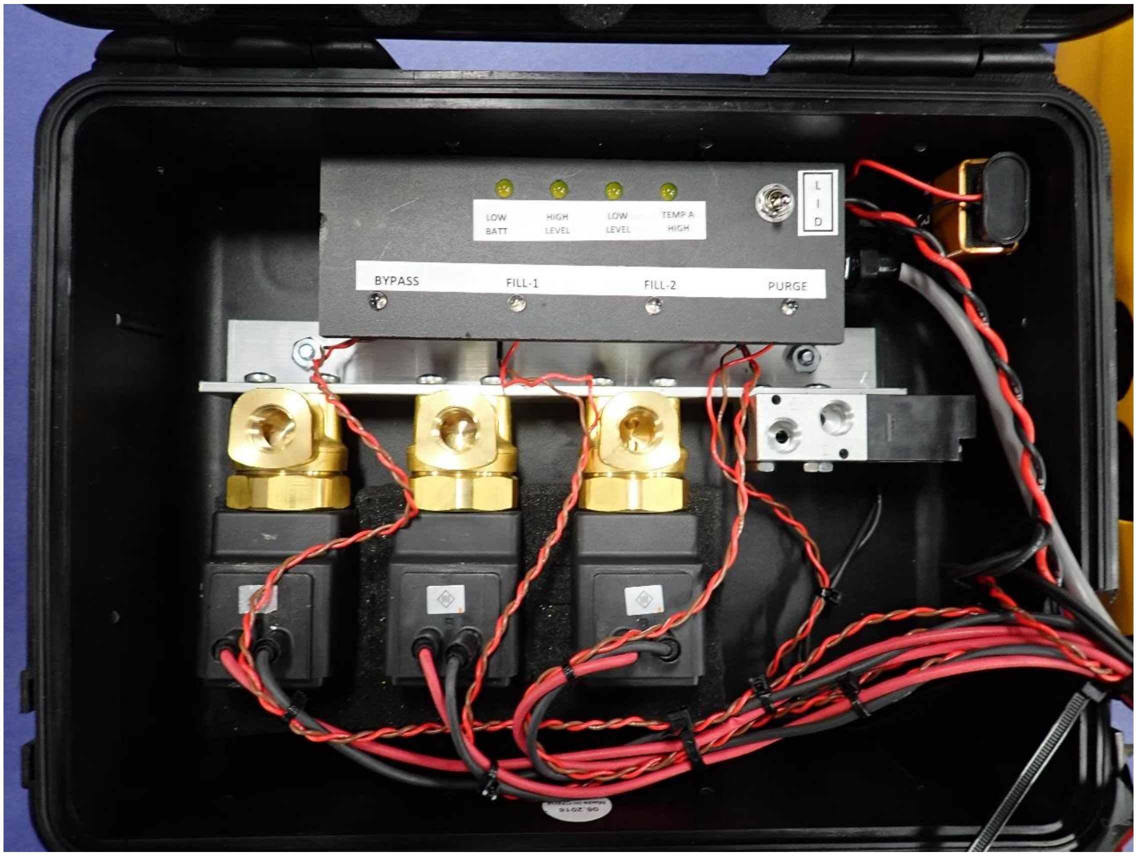
Manufacturer	Product Series	Controller Type	# Alarms (more possible but not cited)
Thermo Scientific	CRYO Plus 1 - 4 Model 7400 Series	LN2 / Temperature	7
	ULT-10140 ULT-7150	Temperature	7
	Cryoextra CE8100	LN2 / Temperature	18
Lakeshore Cryotronics	Model 336	Temperature	2
Cryologic	Freeze Control CL8800	Temperature	2
Planer	Series 300 and 500 Models	LN2 / Temperature	3

Cryogenic LN2 / temperature freezer controller suppliers peer with the TEC 3000 controller.

5.4 Exemplar TEC 3000 controller operation

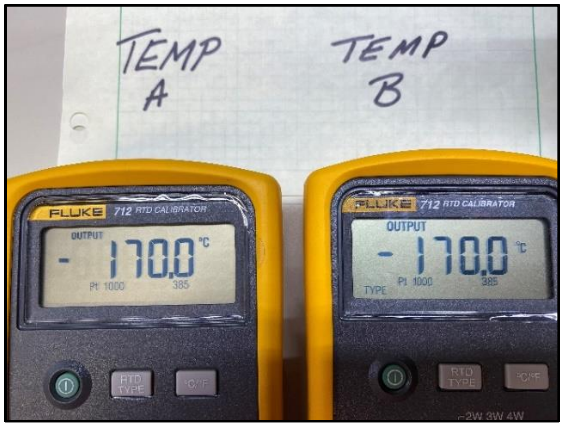
I obtained and analyzed an exemplar TEC 3000 controller to understand firsthand operation, features, and controls. I developed a customized load simulator platform to interface with the TEC 3000 controller. The load platform enables signals to be input to the TEC 3000 per design and varied across the expected range. Actuator output can be commanded to specific levels and alarm output responses observed. The load platform contains two Fluke 712 RTD (resistance temperature detector) calibration meters to provide temperature input signals for Temp A and Temp B inputs. A blood pressure inflation bulb and sleeve bladder combined with a Fluke 719 Pro pressure calibrator is used to source and monitor pressure input to simulate a LN2 level signal. Actual MVE 808 valve solenoid part numbers were assembled for TEC 3000 actuator loads. The load platform includes LEDs to indicate active external alarm interfaces when enabled. Finally, the TEC 3000 controller with load platform is interfaced to the Chart TEC Connect PC utility through a serial interface. This enables the TEC 3000 controller to be monitored externally and provides a mechanism to download history log data from the exemplar TEC 3000 unit.

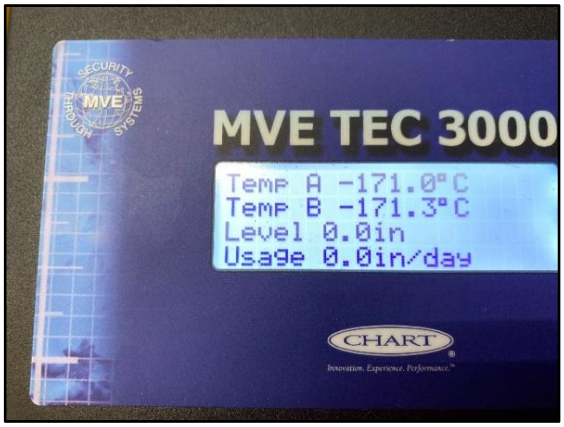
Bench setup with exemplar TEC 3000 unit S/N 369482 with load simulation platform.



Actuator loads for TEC 3000 including alarm monitoring interface LEDs

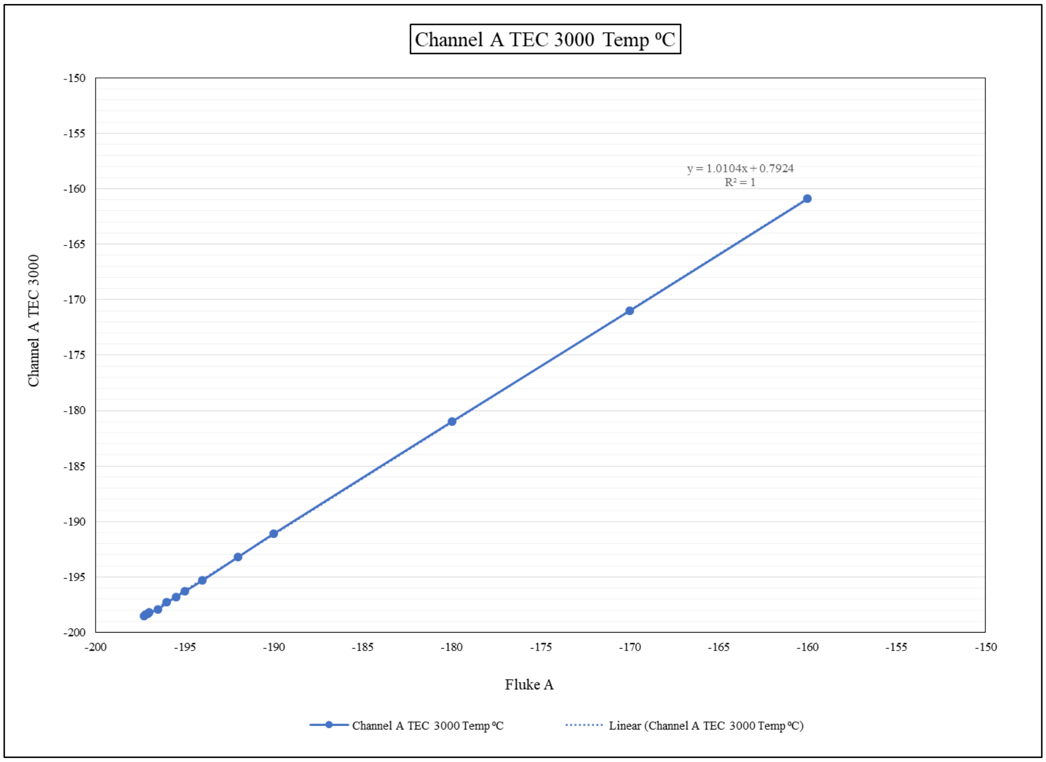
I have conducted trials using the exemplar TEC 3000 controller with load platform interface to correlate measured levels displayed by the TEC 3000 with external, independent measurements. This analysis helps to demonstrate the TEC 3000 controller monitoring capacity and accuracy per design. Temperature inputs were ramped from -160 degrees C down to -197 degrees C using the Fluke 712 RTD calibrator for both Temp A and Temp B inputs.

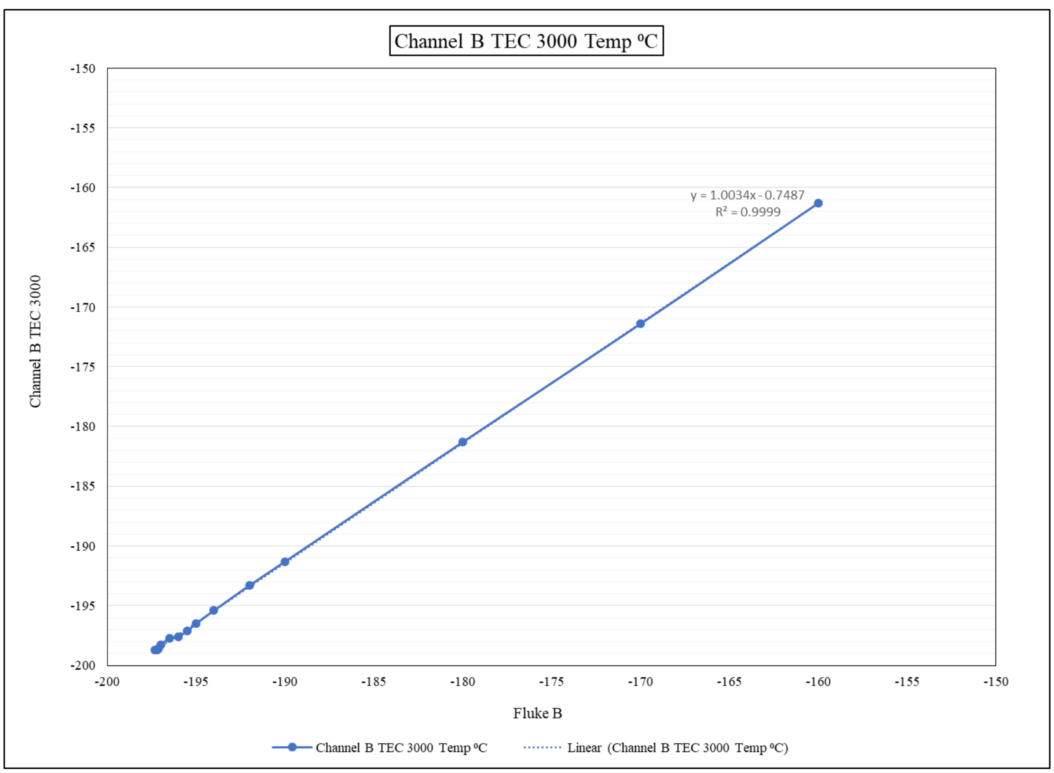




Actuator loads for TEC 3000 including alarm monitoring interface LEDs.

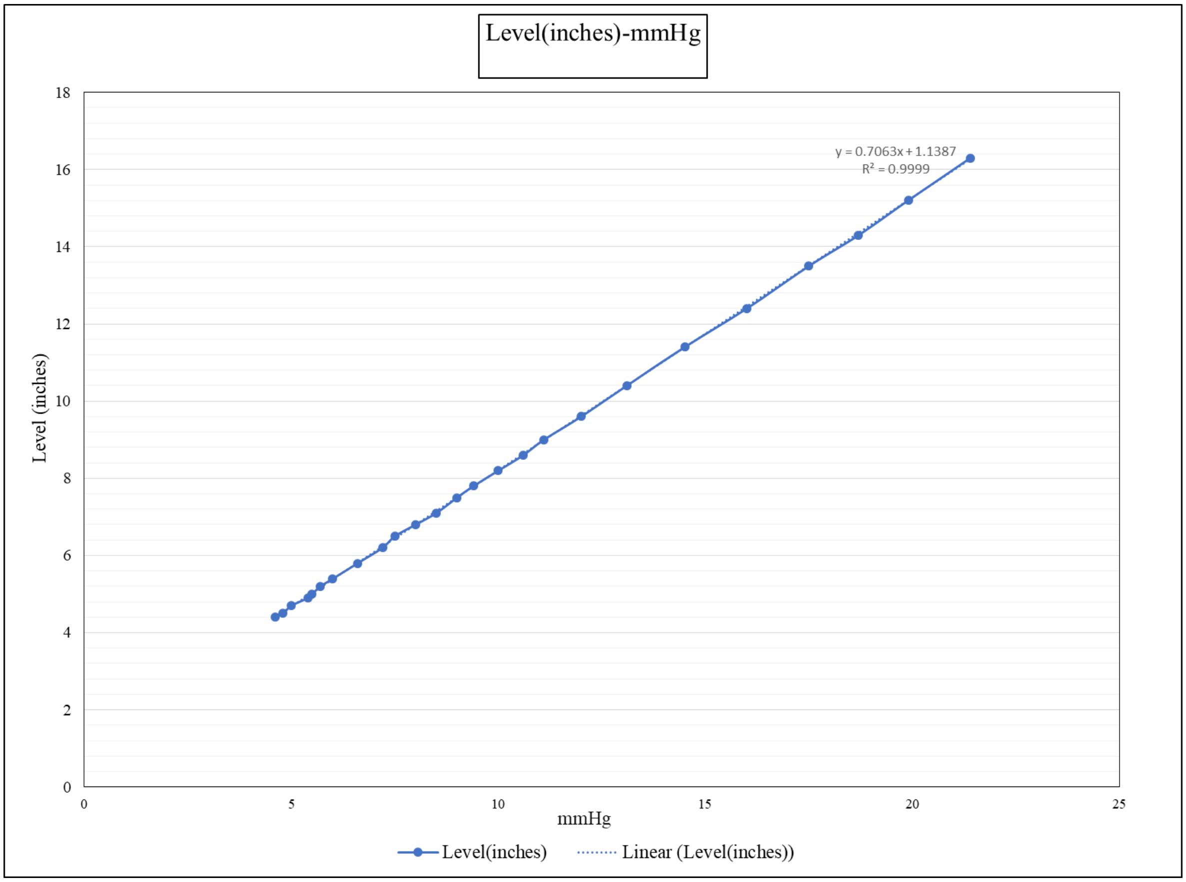
Temperature display output values on the display were monitored and plotted against the input. The plot below shows the correlation of temperature output to input for the exemplar TEC 3000.





Correlation measurements for exemplar TEC 3000 display vs temperature inputs.

I conducted trials with the LN2 level input similar to the temperature input correlation. This was achieved by generating a pressure input to the TEC 3000 LN2 level input with the mechanism described earlier. A pressure input of approximately 21.4 mmHg (0.413 psi) was input to the TEC 3000 LN2 level input and allowed to bleed off over time. Comparing the the level display from the TEC 3000 to external measurements from the Fluke 719 pressure calibrator served as a means to correlate output to input and demonstrate the level measuring and signal processing design for the TEC 3000 controller. A plot showing this correlation from the TEC 3000 exemplar controller is shown below.



Correlation measurements for liquid nitrogen level pressure input vs exemplar TEC 3000 display.

In parallel with both correlation trials for temperature and LN2 level (pressure) input, setpoint and alarm thresholds were adjusted on the exemplar TEC 3000 controller. This served as an effective means to demonstrate the various alarms incorporated with the TEC 3000 failsafe design. Log files to document these trial measurements for temperature, LN2 level and corresponding event codes were recorded and are included with the materials listed in Attachment B.

5.5 Subject MVE 808 - TEC 3000 controller inspection

I inspected the subject Tank 4 MVE 808 system including the TEC 3000 controller installed at PFC during the incident of March 4, 2018. The inspection was conducted at the Exponent Menlo Park, California facility on September 28, 2020, per protocol which had been developed prior between interested parties. The inspection protocol afforded the opportunity examine components from the subject MVE 808 Tank 4 system and evaluate operating capacity of the TEC 3000 controller from Tank 4.

The MVE 808 Tank 4 was observed in addition to components from the tank which had been bagged and labeled during disassembly of the unit and previous inspections. The deformation of the inner wall of Tank 4 was evident. The hole cut in the "false bottom" of the tank during a previous inspection was visible. Ports and connections for LN2 input to the tank and temperature probe tubes were documented. Numerous smaller parts from the tank assembly were viewed in evidence bags.

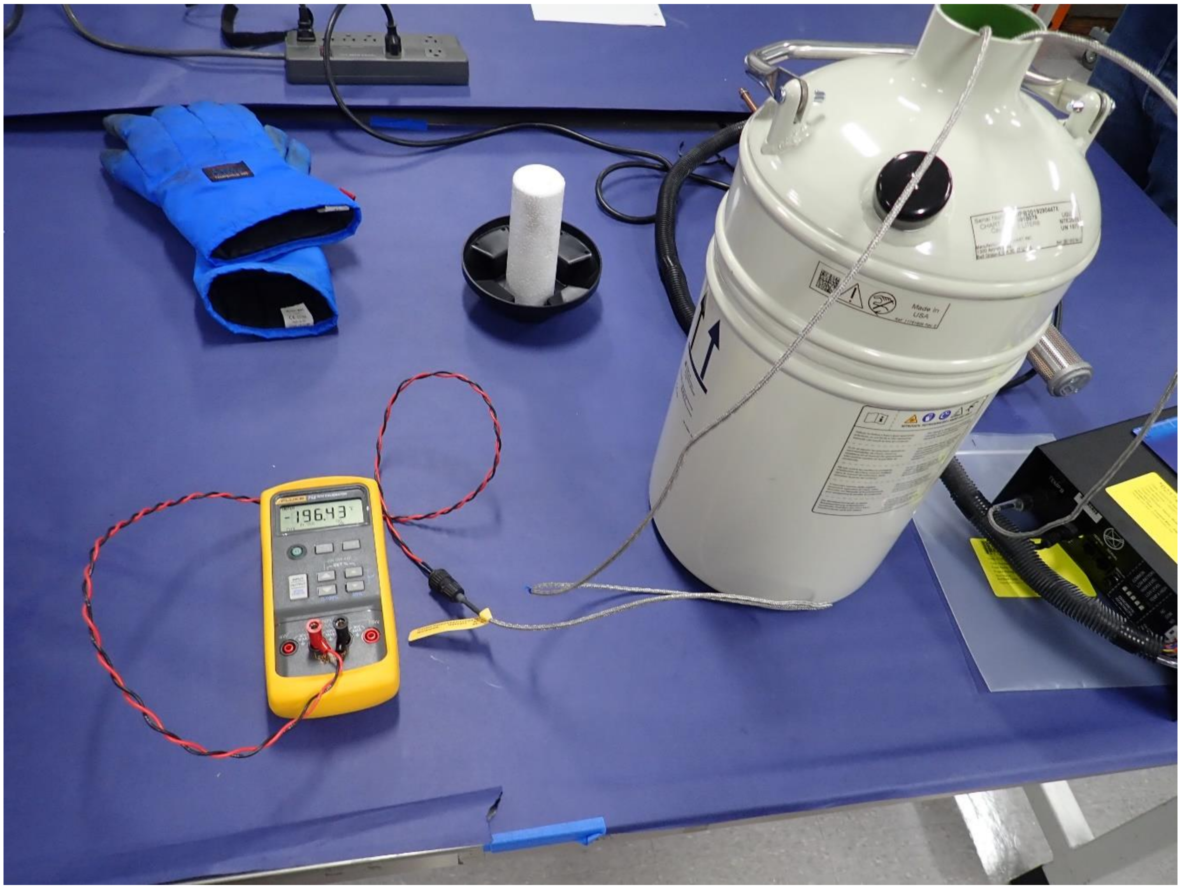
Prior to the functional demonstration of the TEC 3000 controller, I viewed and documented the temperature probes and solenoid loads contained in the plumbing assembly which interface to the TEC 3000 controller. All components appeared to be in good condition without any visible exterior damage. The solenoid harness connections within the plumbing assembly were initially disconnected. These solenoids were reconnected per available wiring schematic diagrams prior to starting the functional demonstration.

Components from subject Tank 4 MVE 808 - TEC 3000 inspection.

5.6 Subject TEC 3000 controller functional inspection

Standalone components

For the TEC 3000 controller functional inspection, I first made certain measurements of the subject temperature sensors and plumbing assembly solenoids isolated from the TEC 3000 controller. This provided a means to assess functionality of the load components prior to interface with the TEC 3000 controller. Both temperature probes were measured at ambient room temperature and then later submersed in a container of LN2. For both sets of readings the Temp A and Temp B probes returned values which indicated that the subject temperature probes are functional. The probes were measured with the Fluke 712 RTD calibrator instrumentation. The measured values are shown in the table below.



Temperature measurement from subject TEC 3000 temperature probe submersed within LN2.

Probe	Ambient Temperature	LN2 Temperature
Temperature A	20.78 °C	-196.43 °C
Temperature B	21.08 °C	-196.42 °C

Temperature measurements from PFC Tank 4 temperature probes;
ambient and LN2 readings.

Solenoids contained in the MVE 808 plumbing assembly were measured for coil resistance. This serves as step to validate that the subject solenoid electrical characteristics are as specified per requirements. The Fill, Bypass and Purge solenoids were measured. All results confirmed that the subject solenoids coil resistances as measured were per product specification. A summary of the measurements compared with specification values is shown in the table below.

Resistance measurement from subject TEC 3000 plumbing assembly Bypass solenoid.

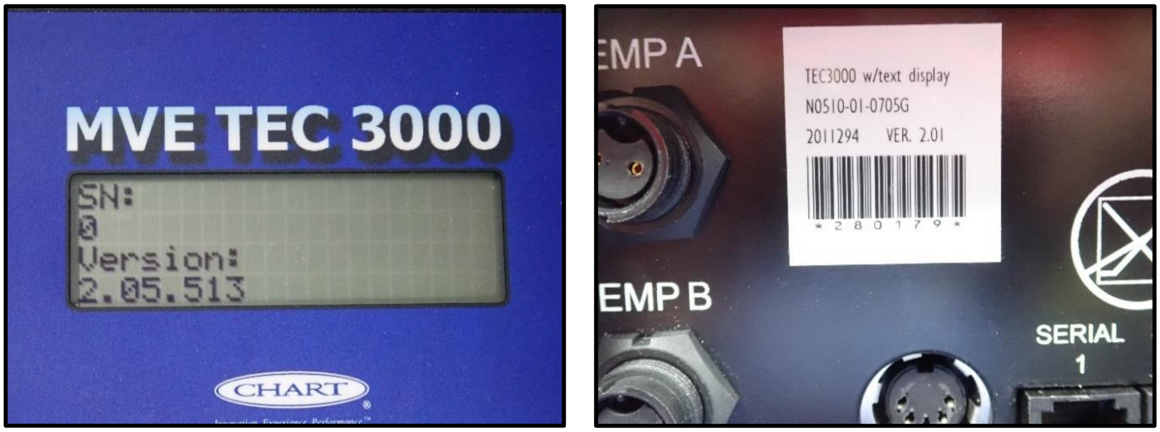
Solenoid	Resistance (ohms)
Fill (2 in parallel)	35.74
Bypass	72.12
Purge	140.33

Summary of subject MVE 808 Tank 4 plumbing assembly resistance measurements.

<u>TEC 3000 configuration assessment</u>

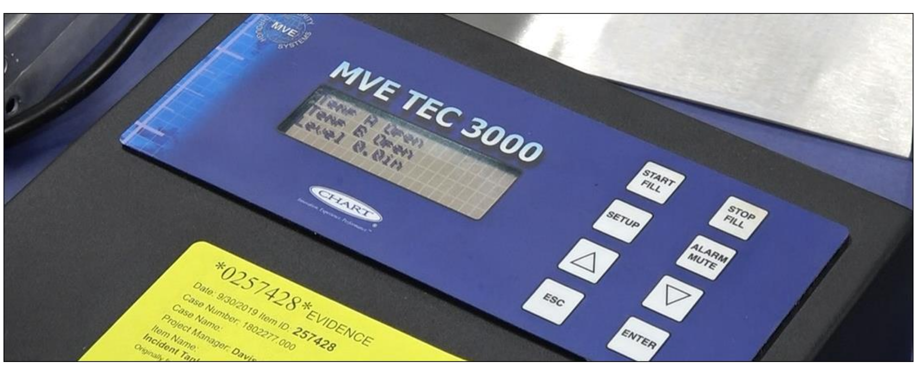
I read configuration settings from the subject TEC 3000 controller to determine what functions within the subject TEC 3000 controller were enabled. The configurations of the subject TEC3000 controller are retrieved from memory by powering the controller and reading data displayed in a sequence of menus accessible through the display keypad. A summary of these results is listed with the materials in Attachment B of this report.

The subject TEC 3000 controller as inspected displayed a Serial Number value of “0,” which did not match the label Serial Number of “280179” located on the identification label on the rear of the unit. Per deposition testimony from Chart engineers [depositions Wade, Junnier] the Serial Number value of “0” may be the result of an electrical interference issue and can also be accompanied by incorrect LN2 level values displayed at zero.



Serial number display of subject TEC 3000 controller unit. Photo at right shows label with part number, serial number and software firmware version as manufactured.

The subject TEC 3000 controller displayed a software firmware version of 2.05.513. The original software firmware distributed with TEC 3000 unit used by PFC was version 2.01 as shown on the rear label. It is my understanding that firmware version 2.05.513 was flashed in to the unit at a prior inspection to facilitate download of the entire range of history log data contained in the unit. With no temperature probes interfaced with the subject TEC controller, the temperature values indicated “Open” on the display. This is an indication that failsafe checks for temperature probe loads were functional within the subject TEC 3000 controller.



Subject TEC 3000 controller display with no temperature probes attached.

I retrieved and documented roughly 60 settings from the subject TEC 3000 controller during the inspection. The configuration settings can be summarized in four different categories:

- Temperature settings
- LN2 level settings
- Feature enables
- Time and date settings

TEC 3000 Temperature settings

I retrieved and reviewed temperature settings from the subject TEC 3000 controller. These settings include high and low temperature alarm thresholds, LN2 saturation temperature, and bypass temperature set point. All of these values were found to be identical to the TEC 3000 default values from the factory as documented in the MVE TEC 3000 Controller Operating and Maintenance Manual.

SUBJECT TEC 3000 TEMPERATURE CONFIGURATIONS	
Temp A High Alarm	-110.0 °C
Temp A Low Alarm	-200.0 °C
Temp B High Alarm	-110.0 °C
Temp B Low Alarm	-200.0 °C
LN2 Saturation Temp	-196.2 °C
Bypass Temp Setpoint	-69.9 °C

Subject TEC 3000 temperature configurations as recorded.

TEC 3000 LN2 level settings

I retrieved and reviewed LN2 settings from the subject TEC 3000 controller. These settings include set point level parameters for Auto Fill operation and thresholds for alarms. These parameters are designed to be configurable to tailor the MVE 808 TEC 3000 fill control to the required application. The subject TEC 3000 operating fill levels from PFC were set 3 inches apart at 12.5 for the high set point and 9.5 inches for the low set point. Thus, with Auto Fill enabled, a fill operation would start once the LN2 dropped below 9.5 inches and stop once the LN2 reached 12.5 in. The high and low set points were established between the alarm limits of 18 inches for the High Level Alarm, and 6.5 inches for the Low Level alarm level. The level offset parameter was decreased from the default of 1.3 inches, set to 0.5 inches.

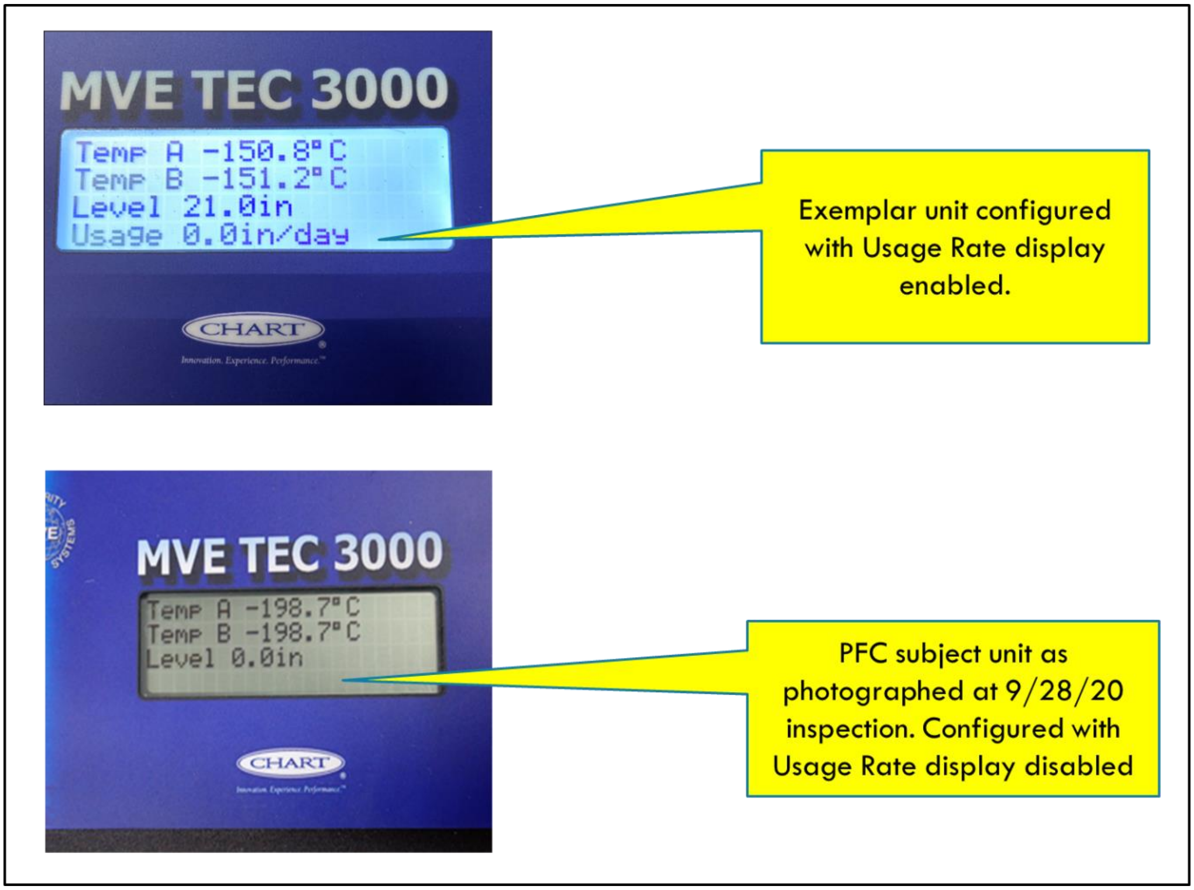
SUBJECT TEC 3000 LEVEL CONFIGURATIONS	
Liquid Display Units	inches
Define 100%	15.0 inches
Define 0%	8.0 inches
High Level Alarm	18.0 inches
High Level Setpoint	12.5 inches
Low Level Setpoint	9.5 inches
Low Level Alarm	6.5 inches
Level Offset	0.5 inches

Subject TEC 3000 level configurations as recorded.

<u>TEC 3000 feature enable settings</u>

I retrieved and reviewed feature enable settings from the subject TEC 3000 controller. These settings govern whether a particular feature of the TEC 3000 is configured to be on or off. Most of the features of the subject TEC 3000 were enabled. Exceptions were the Advanced Fill option and the Display Liquid Usage option. The advanced fill option would be configured if the application required a fill operation to be performed at a specific time interval for a specific period of time. It is unlikely that a user would enable both the Advanced Fill option and the Auto Fill option.

The LN2 usage parameter calculated by the TEC 3000 software algorithm will not be displayed with the Display Liquid Usage option disabled. This configuration setting was also confirmed by observing that only 3 lines of text were present on the display as the fourth line is reserved for the usage calculation as shown in the photo below. Disabling the Display Liquid Usage option would prevent users from regularly monitoring usage rate and thus being able to more easily discern what is normal vs. what is abnormal.



Subject TEC 3000 controller display as configured without LN2 Usage parameter.

A summary of the enable values retrieved and reviewed is shown in the table below.

SUBJECT TEC 3000 ENABLE CONFIGURATIONS	
Temp A Enable	ENABLE
Temp B Enable	ENABLE
Power Failure Alarm Status	ENABLE
Hot Gas Bypass Alarm	ENABLE
Stuck Valve Alarm	DISABLE
Lid Switch Installed	NO
Display Liquid Usage	DISABLE
Liquid Usage Alarm	ENABLE
Alarm Buzzer	ENABLE
Auto Fill Control	ENABLE
Timed Fill	DISABLE

Subject TEC 3000 enable configurations as recorded.

<u>TEC 3000 time settings</u>

I retrieved and reviewed time settings from the subject TEC 3000 controller. The TEC 3000 maintains a time setting which is used to time stamp when alarms occur and is recorded with each entry logged in the event history data. In addition to time of day and date settings, there are entries for Bypass Alarm Time Delay, Lid Switch, Advanced Fill and Stuck Valve Delays of which only the Bypass Alarm Time delay was set. The default value for this setting is 5 minutes. A value of 90 minutes was set for this delay parameter with the subject TEC 3000 controller. This is an extremely long time setting as compared with the default value. The net effect from this setting would be to effectively disable the Hot Gas Bypass Alarm.

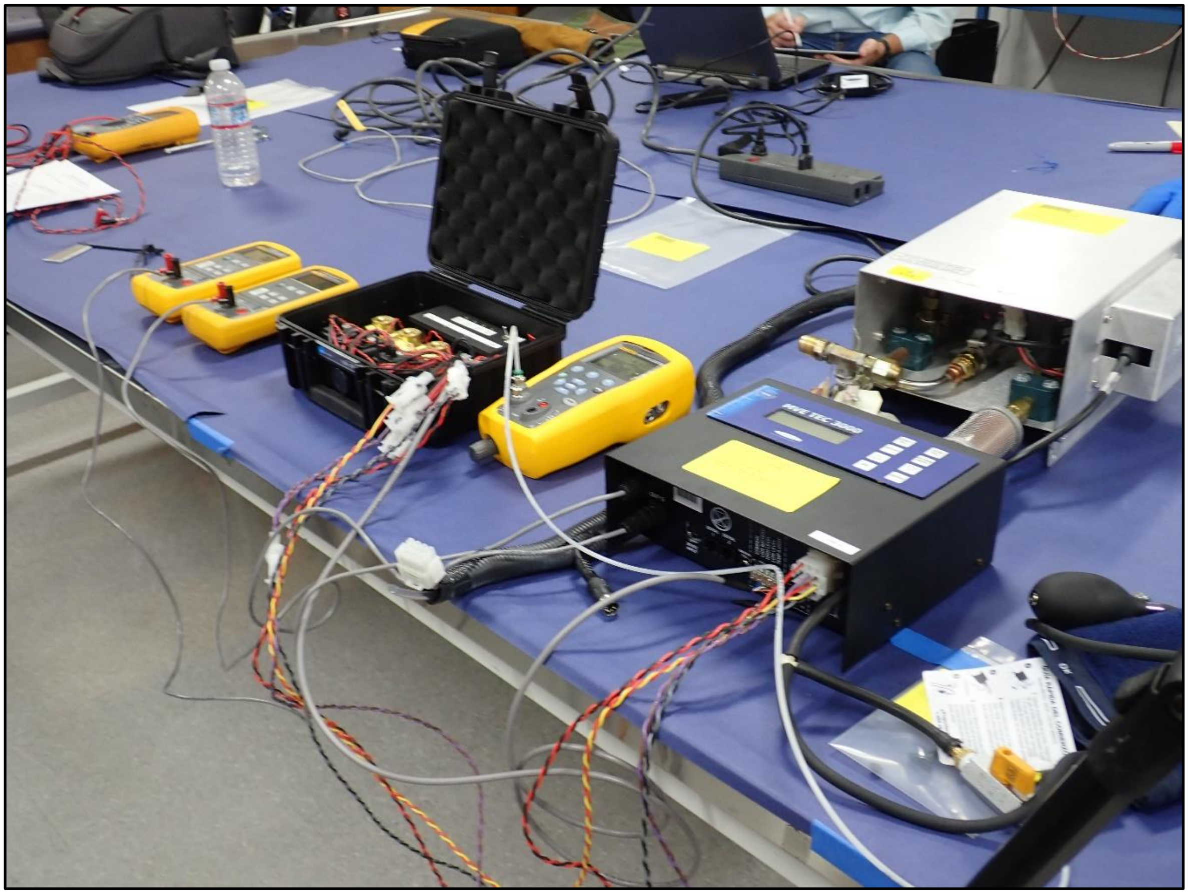
The time of day and date setting parameters were retrieved and are shown in the chart below.

SUBJECT TEC 3000 TIME PARAMETERS	
Bypass Alarm Time Delay	90 min
Time Format (Hour / Min @ reading)	05:51 PM
Year	2020
Month	09
Date	28
Local Time (@ reading)	01 : 43 PM 09/28/20

Subject TEC 3000 time parameters as recorded.

TEC 3000 operation with actual and simulated loads

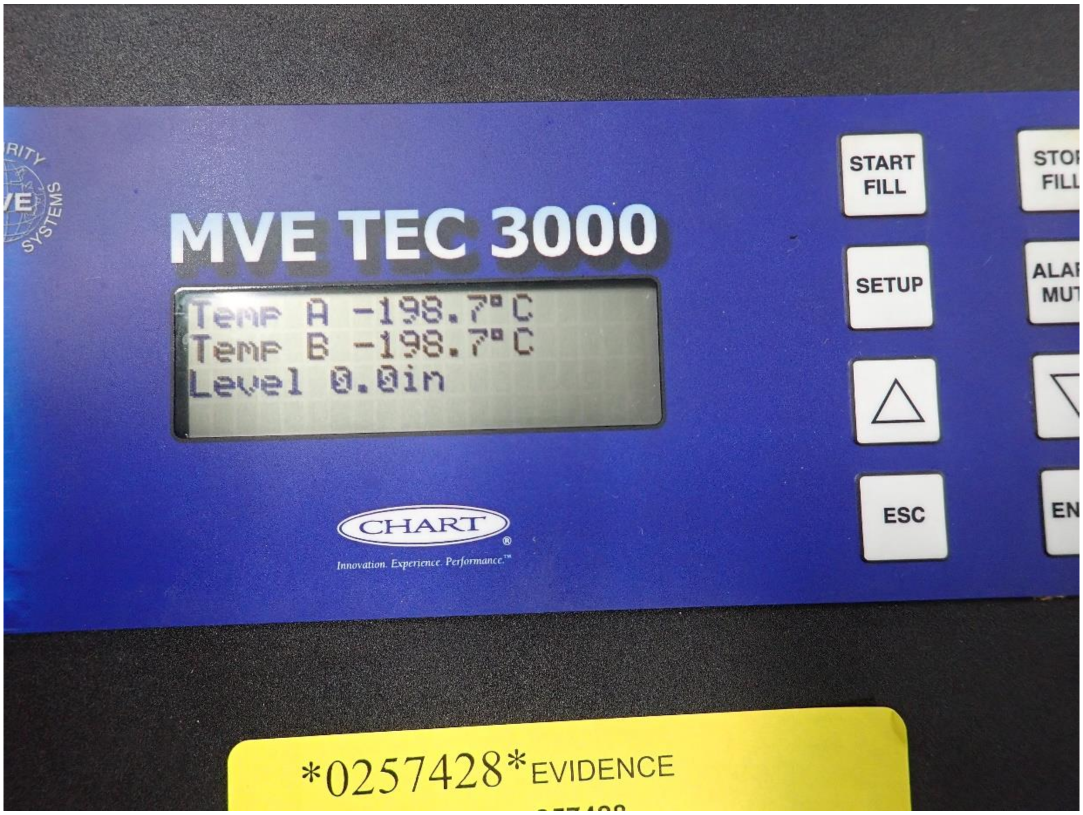
I operated the subject TEC 3000 with actual and simulated loads to observe and document responses from the TEC 3000 controller. The objective was to determine the level of functionality exhibited by the subject TEC 3000 controller. The load platform as described earlier in Section 5.4 was interfaced to the subject TEC 3000 controller during the inspection.



Simulator load platform components interfaced with subject TEC 3000 controller during September 28, 2020 inspection.

Both the set of subject temperature probes and Fluke 712 RTD meters with the simulated load platform were used to evaluate the temperature input monitoring functionality for the subject TEC 3000 controller. For each of these sets of inputs the subject TEC 3000 controller exhibited an inability to accurately sense and display temperature inputs. The subject TEC 3000 controller displayed a fixed or constant value of -198.7 degrees C for any temperature input.

Similarly, I examined the LN2 level monitoring and display functionality. A pressure level of 14.9 mmHg (0.288 psi) was input to the subject TEC 3000 controller LN2 level port. This pressure input eventually bled down to a level of 12.1 mmHg (0.234 psi) during this portion of the inspection. The subject TEC 3000 controller displayed a fixed or constant LN2 level value of 0.0 inches for any simulated pressure level input. The conclusion here was that the PFC subject TEC 3000 controller capacity to sense and accurately report temperature input and LN2 pressure level is not working correctly.



Temperature and liquid nitrogen level display from subject TEC 3000 controller with simulated load inputs.

While operating the subject TEC 3000 controller with the simulated load platform, I observed proper functionality by the failsafe design triggering a Low Level Alarm in response to the LN2 level reading constant at 0.0 inches. In addition, the corresponding outputs for external and global alarms were observed to be active as evident from active LEDs interfaced to the subject TEC 3000 controller external alarm ports. This confirms that an external alarm system such as the Sensaphone Sentinel would respond to alarms from the subject TEC 3000 when connected with both units powered on.

Control output was observed to be functional with the subject TEC 3000 controller. This was confirmed both with the manual fill button on the rear of the controller and "START FILL" and "STOP FILL" buttons on the controller display. Each of these commands was successful in energizing solenoids in the simulator load platform.

I verified the subject TEC 3000 controller functions responsible for data logging and serial communication by performing a data download for the period of time that the subject controller was powered on during the inspection of September 28, 2020. The PC TEC Connect utility was used to connect and successfully download. This data download is included with the Attachment B materials for this report.

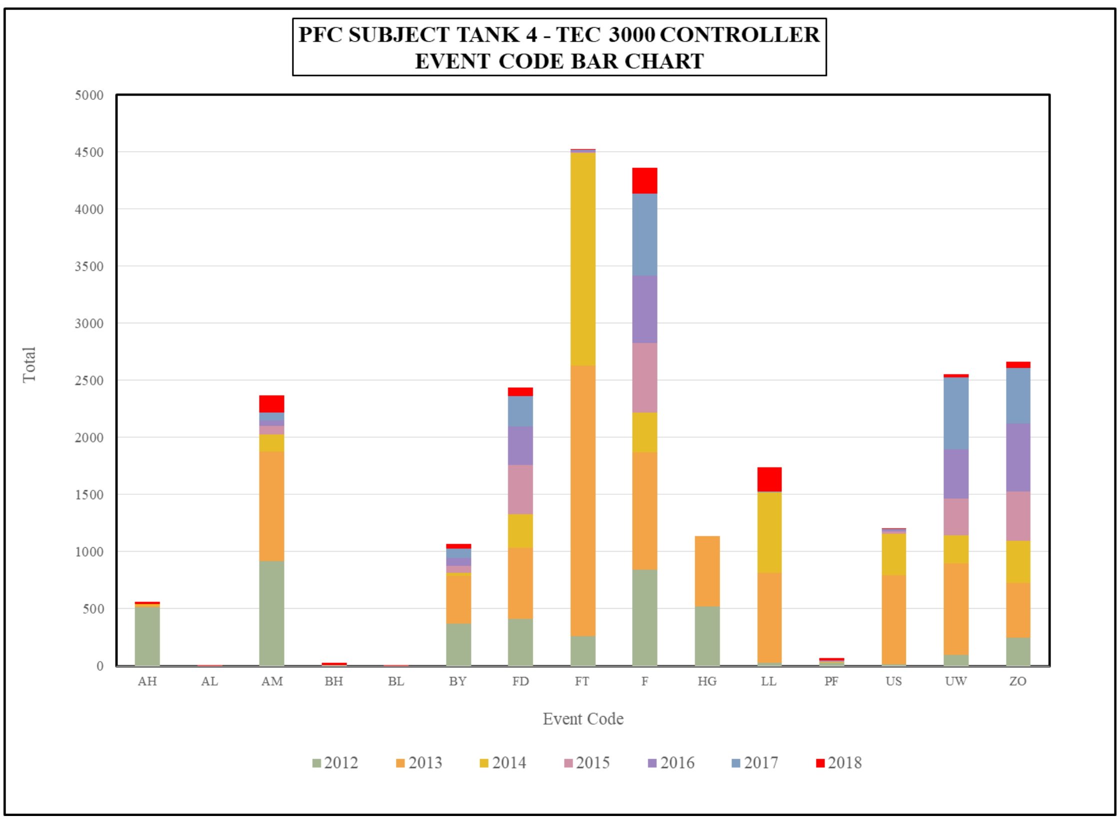
The scope of my investigation regarding the subject TEC 3000 controller was not focused on root cause analysis of any malfunctions observed. Demonstration and assessment of the TEC 3000 failsafe design does not require root cause of observed anomalies. Rather, failsafe is designed to detect specific abnormal conditions regardless of cause and mitigate risks through an appropriate countermeasure.

Where feasible, methods were employed to monitor any abnormal subject TEC 3000 operating characteristics which if present could point to root cause. Ambient electromagnetic field strength emitted from the TEC 3000 was one such measurement. Throughout the functional assessment portion of the inspection, electromagnetic field strengths emitted from the subject TEC 3000 controller during operation were measured and recorded using field strength meters. Measurements from the subject controller were compared to measurements from an exemplar TEC 3000 controller. Average low frequency (less than KHz) field strength was recorded at 165 nanoTeslas. The field strength measurements are consistent with similar measurements recorded from an exemplar TEC 3000 unit.

5.7 Subject TEC 3000 operational history data analysis

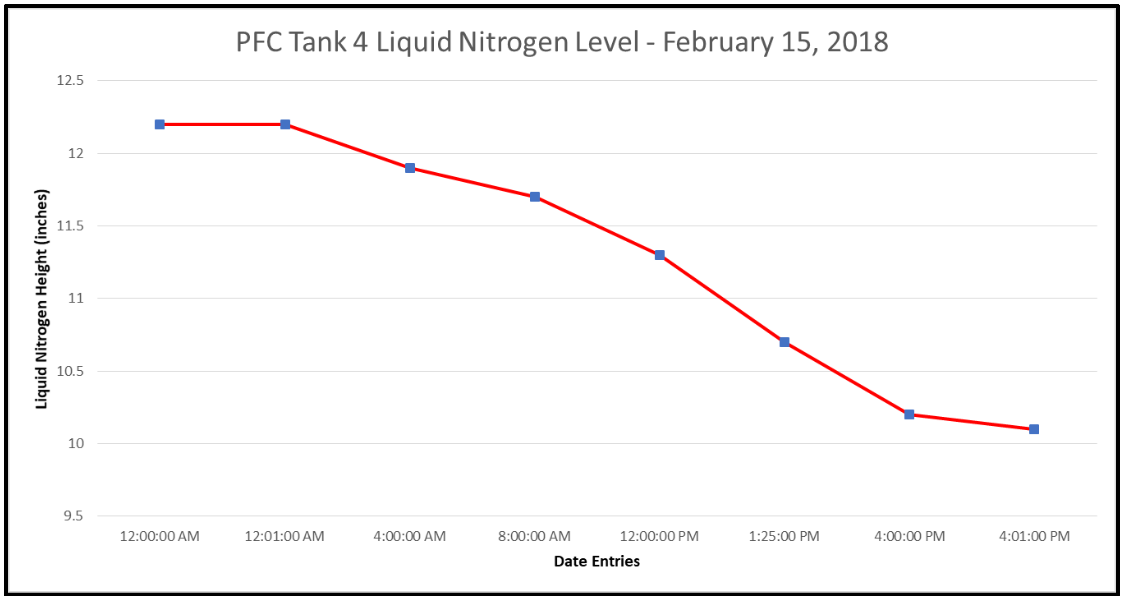
I have obtained operational history data from the subject TEC 3000 controller and daily log records from the subject controller operation. This data was provided through discovery files CHART000127, CHART070093, CHART070095, MSO001998 – MSO002049, and MSO027053. Collectively, this data spans entries recorded of the subject Tank 4 MVE 808 - TEC 3000 controller system operation from April 15, 2012 thru March 4, 2018. The records also capture subject TEC 3000 controller event history from March 4, 2018 through October 18, 2019. After March 2018 the subject TEC 3000 controller was powered during component inspection procedures. The data records cited above are comprised of data files downloaded from the subject TEC 3000 controller via the TEC Connect utility, the PFC Reflections database file and summary reports from the Reflections system.

I have reviewed this data and analyzed it over two general time periods. The first period from April 15, 2012 up to February 15, 2018 and the second period, after February 15, 2018 thru the incident of March 4, 2018. The data shows that during the first period, the subject TEC 3000 controller was fully functional. During this period of time the data records capture events, alarms, temperature measurements, LN2 level measurements and LN2 usage rates indicative of daily operation. Detailed analysis during this roughly six year time period shows the Tank 4 MVE 808 operation was maintained at an average LN2 level of 12.588 inches over 4367 fill commands and an average temperature of -193.1 degrees C for the Temperature A probe location and -195.9 degrees C for the Temperature B probe location. Of the 18 possible alarm events implemented per the TEC 3000 failsafe design, nine alarm events were asserted in the Tank 4 MVE 808 system during this period. The distribution of events tallied per year is shown in the graph below.



Tallied PFC Tank 4 TEC 3000 event codes from April 15, 2015 through March 26, 2018

Analysis of the available data from February 15, 2018 shows that up to the point of the subject TEC 3000 controller power interruption loss at the system timestamp of 6:45 p.m., the controller was functioning properly. Temperature readings are shown to read at -195.8 degrees C and -196.1 degrees C for Temperature A and B probes respectively. These values are distinct from the -198.7 degrees C value observed following the power loss. The LN2 level is shown gradually decreasing over the course of the day from 12.2 inches down to 10.1 inches prior to the event entry reporting the power interruption. As a result of the decrease in LN2 level, the calculated usage level changed from a more reasonable 1.4 inches/day to 10.4 inches/day resulting in a Usage Warning, "UW" event code. The calculated usage level was not displayed due to the value of the display configuration setting.



PFC Tank 4 TEC 3000 liquid nitrogen levels recorded on February 15, 2018 up to power interruption.

Record #	Unit ID	Date	Time	Temp A	Temp B	LN2 Level	LN2 Usage	Event Codes
29372	200	2/15/18	12:00 AM	-195.8	-196.1	12.2	1.4	ZO
29371	200	2/15/18	12:00 AM	-195.8	-196.1	12.2	1.4	ZO
29370	200	2/15/18	12:01 AM	-195.8	-196.1	12.2	1.4	
29369	200	2/15/18	4:00 AM	-195.8	-196.1	11.9	1.4	
29368	200	2/15/18	8:00 AM	-195.8	-196.1	11.7	1.4	
29367	200	2/15/18	12:00 PM	-195.8	-196.1	11.3	1.4	
29366	200	2/15/18	1:25 PM	-195.8	-196.1	10.7	10.2	UW
29365	200	2/15/18	4:00 PM	-195.8	-196.1	10.2	10.2	UW
29364	200	2/15/18	4:01 PM	-195.8	-196.1	10.1	10.2	F UW
280	200	2/15/18	6:45 PM	-273.1	-273.1	0	10.2	LL AL BL PF FD AM
279	200	2/15/18	6:46 PM	-198.7	-198.7	0	0	

PFC Tank 4 TEC 3000 event codes and data recorded on February 15, 2018 up to power interruption.

At the system timestamp of 6:45 p.m. on February 15, 2018, the subject TEC 3000 controller history data captured a power interruption indicated by a "PF" event code. This code is accompanied by a Low Level Alarm "LL", Temp A Low Alarm "AL", Temp B Low Alarm "BL", Fill Disable "FD", and Alarm Mute disable "AM." Temperature readings are reported at -273.1 degrees C, which most likely is the cause for the AL and BL alarms. Per deposition testimony of J. Junnier, this may coincide with the occurrence of the Serial Number value being set to "0."

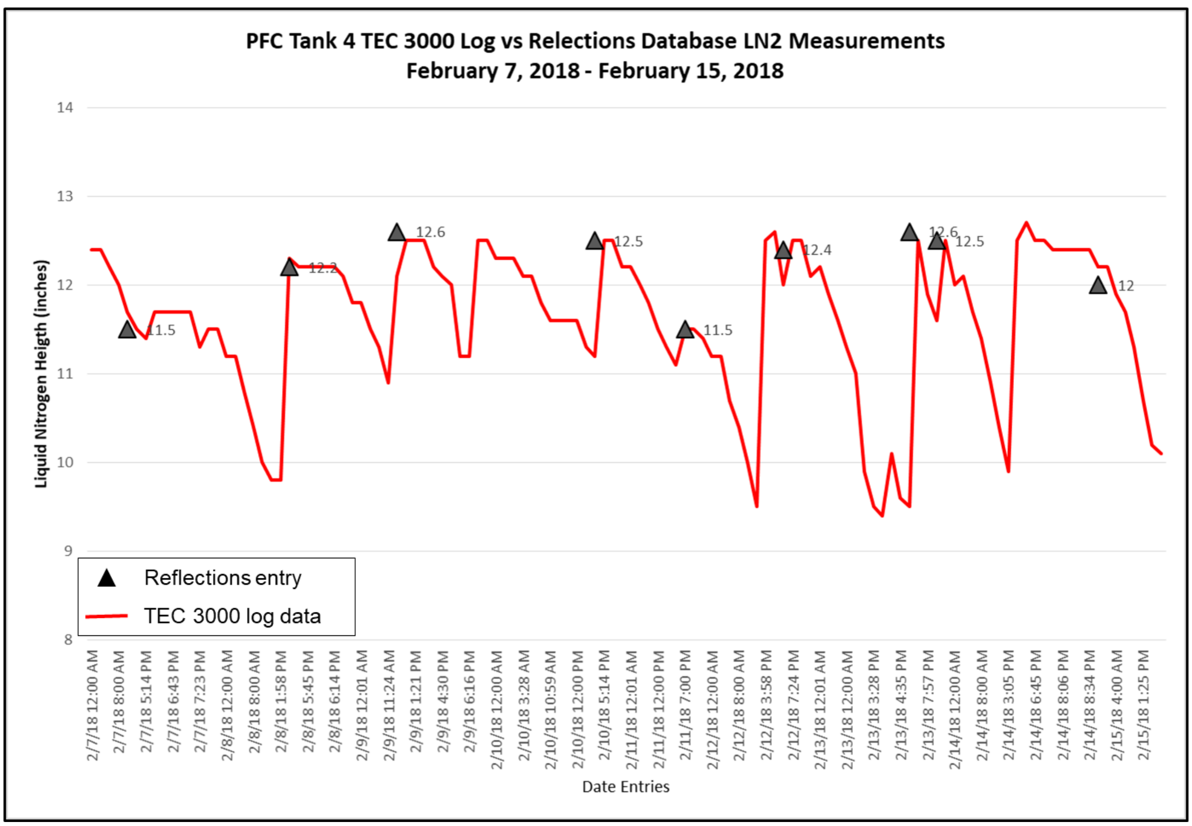
The second portion of data I have analyzed occurs from the timestamp of 6:45 p.m. on February 15, 2018, through March 4, 2018. During this period, the subject TEC 3000 controller exhibits an inability to measure and report temperature and LN2 level readings correctly. Both Temperature A and Temperature B measurements are reported at -198.7 degrees C, while the LN2 level is reported at 0.0 inches. These readings are the same that I observed during the component inspection of September 28, 2020. The LN2 level of 0.0 inches results in a constant Low Level Alarm, "LL" while the controller is powered. The downloaded data record from February 15, 2018 through March 4, 2018 shows that the subject TEC 3000 subject controller was powered and then unpowered a total of 21 times to perform manual fill operations of varying duration. A manual fill operation as evident by the "F" event code in the download data was commanded daily during this period with the exception of February 21 and February 24, 2018 where the download data shows that no use of the subject TEC 3000 controller occurred.

Record #	Unit ID	Date / Time	Temp A	Temp B	LN2 Level	LN2 Usage	Event Codes
260	200	2/15/2018 7:39 PM	-198.7	-198.7	0	0	LL PF FD AM
259	200	2/16/2018 5:50 PM	-198.7	-198.7	0	0	
258	200	2/16/2018 5:50 PM	-198.7	-198.7	0	0	F
257	200	2/16/2018 5:51 PM	-198.7	-198.7	0	0	F LL
256	200	2/16/2018 5:51 PM	-198.7	-198.7	0	0	F LL AM
255	200	2/16/2018 6:20 PM	-198.7	-198.7	0	0	F LL
254	200	2/16/2018 6:20 PM	-198.7	-198.7	0	0	F LL AM
253	200	2/16/2018 6:45 PM	-198.7	-198.7	0	0	LL FD AM
252	200	2/16/2018 6:45 PM	-198.7	-198.7	0	0	LL PF FD AM
251	200	2/17/2018 4:40 PM	-198.7	-198.7	0	0	
250	200	2/17/2018 4:40 PM	-198.7	-198.7	0	0	F
249	200	2/17/2018 4:41 PM	-198.7	-198.7	0	0	F LL
248	200	2/17/2018 4:42 PM	-198.7	-198.7	0	0	F LL AM
247	200	2/17/2018 5:10 PM	-198.7	-198.7	0	0	F LL
246	200	2/17/2018 5:10 PM	-198.7	-198.7	0	0	F LL AM
245	200	2/17/2018 5:39 PM	-198.7	-198.7	0	0	LL FD AM
244	200	2/17/2018 5:39 PM	-198.7	-198.7	0	0	LL PF FD AM
243	200	2/18/2018 4:53 PM	-198.7	-198.7	0	0	
242	200	2/18/2018 4:53 PM	-198.7	-198.7	0	0	F
241	200	2/18/2018 4:54 PM	-198.7	-198.7	0	0	F LL
240	200	2/18/2018 4:54 PM	-198.7	-198.7	0	0	F LL AM
239	200	2/18/2018 5:23 PM	-198.7	-198.7	0	0	F LL
238	200	2/18/2018 5:23 PM	-198.7	-198.7	0	0	F LL AM
237	200	2/18/2018 5:27 PM	-198.7	-198.7	0	0	LL FD AM
236	200	2/18/2018 5:27 PM	-198.7	-198.7	0	0	LL PF FD AM

PFC Tank 4 TEC 3000 event codes and data recorded from February 15 through February 18, 2018. Note each entry highlighted in red indicates were the subject TEC 3000 controller was powered off.

I have analyzed and compared data records available from the subject TEC 3000 controller download and the PFC Reflections database for the month of February 2018 through the incident of March 4, 2018. This comparison reveals that the method of recording LN2 levels was insufficient for accurately monitoring LN2 usage levels. Per the CHART MVE TEC 3000 Operation and Technical Manual, monitoring of LN2 usage and the associated alarm serves as an early warning to potential vacuum failure.

Dr. Conaghan, when asked in his deposition about the frequency of checking the Tank 4 usage rate, responded, "We didn't check usage." The recording method employed by PFC staff as described in deposition testimony by Dr. Conaghan and PFC Embryologist G. Cirimele stated that recordings were made after checking and filling Tank 4 both before the incident of February 15, 2018 and after that until March 4, 2018. By recording the level of LN2 only after the fill operation, the records will always show a "full" level. An alternative would be to check and record the level of LN2 prior to filling and after completion of the filling operation. This would provide an indication of how much LN2 was being depleted between fillings (usage rate) and serve as an indicator if problems were developing with the tank. An overlay of data leading up to the incident of February 15, 2018 shown in the plot below illustrates how the consistent data of the once-a-day fill level record obscures the fact that the rate of LN2 level change (usage) is very dynamic. The subject TEC 3000 usage level value was not displayed based on the disabled setting of the usage level display configuration.



PFC Tank 4 TEC 3000 LN2 levels recorded from February 7 through February 15, 2018 shown with the red trace. The triangle symbols denote the Reflections data entered by PFC staff at the end of each day.

5.8 Chart MVE TEC 3000 troubleshooting corrective action procedures

I have reviewed Chart documentation describing recommendations for MVE TEC 3000 preventive maintenance and troubleshooting steps in the event of abnormal operation. Various operational symptoms are cross referenced with possible causes, fixes, and instructions on how to implement or execute the recommended fix. The TEC 3000 controller includes alarms to alert for several of these abnormal conditions. The cross referenced fix recommendations and instructions are an outcome of the failsafe design analysis. The directive to seek help by reporting technical issues to an MVE distributor or technical service are ultimately noted in the event that recommended fixes leave the issue unresolved.

Depositions referenced by Chart engineers R. Gonzalez, B. Wade, and J. Junnier make reference to procedures adopted by Chart to perform troubleshooting of MVE TEC 3000 field issues. When notified of field issues such as Serial Number equal to 0, LN2 level equal to 0, or tanks not filling, customers were notified and instructed with guidelines to troubleshoot. A Return Material Authorization or RMA process within Chart managed customer returns of TEC 3000 controller units resulting in customers receiving either repaired or replacement TEC 3000 units. In some cases, Chart personnel would work with controller manufacturer Extron to identify the root cause of certain TEC 3000 issues.

The event history download from the subject controller indicates that alarms on the afternoon of February 15, 2018 were accompanied by a power interruption or PF event. Prior to this the system had been commanded to Fill and LN2 level measured at 10.2 inches. Per deposition testimony from Dr. Conaghan, “My decision was to turn off the controller because it was in a constant state of alarm.” The low level alarm and LN2 reading of 0.0 inches combined with visual observation that LN2 was at an appreciable level as discerned by manual measurement should have been an indication that the TEC 3000 LN2 level measurement was not working properly. Chart had preventative maintenance recommendations, troubleshooting guidelines and product return and replacement procedures in place. If PFC had notified Chart of the incident of February 15, 2018 then troubleshooting would have been initiated resulting in repair or replacement of the subject TEC 3000 controller. Instead, the decision by PFC was to unplug the controller and resort to manual fill and monitoring procedures.

6. Discussion of Opinions

I have formed the following opinions as a result of my analysis and investigation of the Chart MVE 808 TEC 3000 Controller system and including the subject PFC Tank 4 TEC 3000 controller involved in the incident of March 4, 2018. I have reached the following opinions to a reasonable degree of engineering certainty.

1. The Chart MVE 808 TEC 3000 controller design provides control functions and failsafe functions to support the operation of the Chart MVE 808 liquid nitrogen (LN2) cryogenic freezer. The design is commonplace and consistent with peer cryogenic freezer controls. The TEC 3000 is not unreasonably dangerous in its design and manufacture. The Chart MVE 808 TEC 3000 controller is safe in design and manufacture for its intended uses.

- Control design for the TEC 3000 controller was examined and shown to have capacity to process sensor input measurements, perform calculations based on these measurements per requirements and control outputs necessary for cryogenic MVE 808 freezer operation.
- Failsafe design for the TEC 3000 controller was examined and shown to have capacity to detect certain events of concern and provide an alarm to the system user. Examined supporting information, including DFMECA documentation, indicates that failsafe requirements were considered during the product design process and supporting features were implemented accordingly.
- The Chart MVE 808 - TEC 3000 Controller design has been compared with peer designs and has been found to be comparable and in some cases provide greater functionality than peer designs.

2. The subject PFC Tank 4 TEC 3000 controller demonstrated both control and failsafe functionality prior to events involving the controller which occurred on February 15, 2018.

- Records downloaded from the subject TEC 3000 controller show operation of the subject MVE 808 - TEC 3000 controller system for a period of approximately 6 years from 2012 through February 2018.
- Records downloaded from the subject TEC 3000 controller show measurement data for temperature and LN2 levels and fill control operations performed by the subject TEC 3000 controller during this approximately six-year period of time.
- Records downloaded from the subject TEC 3000 controller show various event notifications, as well as alarm notifications for various conditions during this approximately six-year period of time.

3. Changes in LN2 usage level calculations from the subject TEC 3000 controller leading up to events occurring on February 15, 2018 were not displayed.

- Records downloaded from the subject TEC 3000 controller show several Usage Warnings occurred during the month of February 2018 leading up to February 15, 2018 as a function of changes in calculated LN2 usage level.
- Given that the TEC 3000 controller was configured with the "Display Liquid Usage" option disabled, the PFC staff would have been unable to monitor LN2 usage levels from the controller display.
- The changes in LN2 usage levels preceding the incident of February 15, 2018 served as an early indication of pending issues with Tank 4.

4. The subject PFC Tank 4 TEC 3000 controller continued to demonstrate failsafe and manual control functionality during the time from events on February 15, 2018 thru the time of the tank failure incident reported on March 4, 2018 and beyond.

- The subject PFC Tank 4 TEC 3000 controller demonstrated failsafe functionality by indicating various alarms and status codes signifying abnormal conditions when the controller measurements stopped working properly on February 15, 2018.
- The subject PFC Tank 4 continued to demonstrate failsafe functionality when powered after February 15, 2018 with a Low Level alarm consistent with the abnormal condition of the LN2 level constant at a value of 0.
- Manual fill commands were functional from February 15, 2015 through the incident of March 4, 2015.

5. PFC personnel did not notify Chart immediately after the incident on February 15, 2018 resulting in the subject TEC 3000 controller entering a constant state of alarm. Chart would have proceeded with troubleshooting recommendations and service or return procedures if notified by PFC promptly.

- Chart documentation and correspondence outline steps recommended for troubleshooting TEC 3000 controller issues.
- PFC response to TEC 3000 abnormal operation observed initially on February 15, 2018 was to unplug the controller.

6. The manual monitoring method employed by PFC before and after the event involving the subject controller on February 15, 2018 was insufficient to accurately monitor and record LN2 usage levels during this period of operation.

- The PFC procedure to recording the LN2 level after the fill operation will always create a record showing that Tank 4 is at its "full" or target level around 12.5 inches.
- This method does not capture how much LN2 was depleted (usage rate) between fill operations.

- Recording the LN2 prior to and after the fill operation would be more effective in monitoring LN2 usage rate.

7. Conclusions

In summary, I have analyzed and investigated the Chart MVE 808 cryogenic freezer and TEC 3000 control system involved in the incident of March 4, 2018 at Pacific Fertility Center (PFC) in San Francisco, California. I have concluded that the subject MVE 808 - TEC 3000 controller was fully functional for the nearly six year period from April 15, 2012 through February 15, 2018. I have confirmed that the subject MVE 808 - TEC 3000 controller experienced an event on February 15, 2018 resulting in the inability of the TEC 3000 controller to properly report measurements for temperature and LN2 inputs. In addition, serial number information retained in the unit is reported incorrectly as “0.” I have concluded that the failsafe design of the subject TEC 3000 controller has remained functional prior to and after the event of February 15, 2018. This is evident from the Usage Warning events logged prior to the event of February 15, 2018 and the consistent Low Level alarm issued by the TEC 3000 controller after February 15, 2018 through March 4, 2018. I have concluded that observation and recording of LN2 usage levels preceding the event of February 15, 2018 were not performed and if had been conducted, may have served as a potential indicator of pending LN2 issues with Tank 4.

These opinions are expressed with a reasonable degree of engineering certainty based on my engineering educational background, industry affiliation, and development and design experience of control systems. I reserve the right to revise these opinions and offer new opinions as additional information becomes available. Finally, I may use any or all of the materials listed in Attachments A and B as exhibits, if needed, at the time of trial.

Sincerely,

Eldon G. Leaphart

Attachment A

Materials Received in In re Pacific Fertility Center

Pleadings

- 2020-07-13 Download File Materials *(926 document files)*

1. PFC Plaintiff Complaint
2. Third Amended Complaint

Discovery

- 2020-07-13 Download File Materials *(187 document files)*

Deposition Transcripts

- 2020-07-13 Download File Materials *(531 document files)*
- 2020-09-30 Download File Materials *(221 document files)*

3. Christine Allen
4. Jennifer Andres
5. Barry Behr
6. Frank Bies
7. Christopher Brand
8. Jeff Brooks
9. Katherin Buchanan
10. Philip Chenette
11. Gina Cirimele
12. Joseph Conaghan
13. Mayah Curtis
14. Jeffery Dresow
15. Rosalynn Enfield
16. Erin Fischer
17. Carolyn Givens
18. Ramon Gonzalez
19. Keith Gustafson Vol. 1
20. Keith Gustafson Vol. 2
21. Jinnuo Han
22. Carl Herbert
23. Susan Hertzberg
24. Allison Hubel
25. Heather Huddleston
26. Nicholas Jewell
27. Justin Junnier
28. Anand Kasbekar
29. Liyun Li
30. Shuangge Ma
31. Greg Mueller

32. Ashley Parsell
33. Kevin Parsell
34. William Pickell
35. Jean Popwell
36. Chloe Poynton
37. Alden Romney
38. Isabelle Ryan
39. Eldon Schriock Vol. 2
40. Eldon Schriock Vol. 3
41. Arun Sharma
42. Adrienne Sletten
43. Stephen Somkuti
44. Duane Steffey
45. Brendon Wade

Chart Document Production

- 2020-07-13 Download File Materials *(2977 document files)*
- 2020-09-16 Download File Materials *(2 document files)*

46. Chart MVE 808 - TEC 3000 Engineering Drawings; Bates Ref: CHART000061-000077, CHART 000078-000126
47. TEC 3000 Data Download #1; Bates Ref: CHART000127
48. TEC 3000 Data Download #2 and #3; Bates Ref: CHART070093 & CHART070095
49. MVE TEC 3000 Operation and Maintenance Manual; Bates Ref: CHART000701-000860
50. Chart FMEA Materials; Bates Ref: CHART001432
51. Chart MVE-TEC 3000 Functional Test; Bates Ref: CHART044297-044317
52. Intertek Chart EMC Test Report; Bates Ref: CHART037672-037747
53. Chart TEC 3000 Firmware Version 2.02 Engineering Test Report; Bates Ref: CHART014175-014254

Expert Reports

- 2020-07-13 Download File Materials (*15 document files*)

54. Christopher Brand
55. Keith Gustafson
56. Anand Kasbekar PhD

Other Party Documents

- 2020-07-13 Download File Materials (*3050 document files*)

57. Extron DFMEA; Bates Ref: EXTRON005744
58. CAP Submitted Report 2018-03-23; Bates Ref: MSO000081-MSO000088
59. Maintenance Records for Storage Tanks; Bates Ref: MSO000094-MSO000147
60. Tank 4 Photos; Bates Ref: MSO026714-MSO026778

61. Overnight Usage Chart Tank 1 – Tank 8; Bates Ref: MSO011014

Miscellaneous

- 2020-09-16 Download File Materials (*1 document file*)
- 2020-09-17 Download File Materials (*1 document file*)

62. Chart TEC 3000 Firmware Version 2.01
63. Chart TEC 3000 Firmware Version 2.05
64. J. Cauthen November – December 2019 Inspection Photographs

Defendant Expert Rule 26 Reports

- 2020-11-19 Download File Materials

65. Dr. Franklin Miller
66. Dr. Grace Centola
67. John Cauthen
68. Dr. Eve Feinberg
69. Ron Parrington

Attachment B

Materials Reviewed or Generated for In re Pacific Fertility Center

1. CV – Eldon G. Leaphart
2. Testimony List – Eldon G. Leaphart
3. Deposition summaries
4. Photographs, video, notes, and measured data – Carr Engineering, Inc., PFC Component Inspection, September 28, 2020
5. Photographs – Carr Engineering, Inc., Exemplar TEC 3000 Controller Photos, September 28, 2020
6. Data – Carr Engineering, Inc., Exemplar TEC 3000 Controller Download Data, October, 2020
7. Data – Carr Engineering, Inc., Exemplar TEC 3000 Measurement Data, October 2020
8. Data – Carr Engineering, Inc., Subject TEC 3000 Log Data Analysis, October 2020
9. Datasheet – MDL-20464 Display Driver IC
10. Datasheet – MPX10DP Pressure Transducer IC
11. Datasheet – PIC 18F6722 Microcontroller Datasheet
12. Datasheet – PN 14224611S Solenoid Valve
13. Datasheet – PN 13284954S Purge Solenoid Valve
14. Manual – Fluke 712 RTD Calibrator Manual
15. Manual – Fluke 719 Pro Pressure Calibrator Manual
16. Manual – Lakeshore Cryogenic Model 336 Manual
17. Manual – Themo Scientific Model 7400 Series Operating Manual
18. Brochure – Themo Scientific Cryopreservation Storage Equipment
19. Manual – Themo Scientific Model ULT Series Operating Manual
20. Brochure – Cryologic Freeze Control Freezer Systems Brochure
21. Manual – Planer Model 300 and 500 Series Manual
22. Manual – Themo Scientific Cryoextra CE8100 Operating Manual
23. Manual – Sensaphone Sentinel Operating Manual
24. Excerpt – IEC 61000-6-4 EMC Generic Standards, edition 3.0
25. Excerpt – IEC 60601-1-2 Medical Electrical Equipment, edition 4.0
26. Deposition – Deposition Transcript – Eldon G. Leaphart, In re Pacific Fertility Center, November 18, 2020

Attachment C

Curriculum Vitae for Eldon G. Leaphart

Eldon G. Leaphart

- Bachelor of Science – Electrical Engineering, The Ohio State University (1987)
- Master of Science – Electrical Engineering; Control Systems, The Ohio State University (1991)

Specialized Professional Competencies

- Specification, design, test, and evaluation of electro-mechanical control systems for motor vehicles including powertrain, safety, steering, handling, and braking systems
- Specification, design, test, and evaluation of embedded software for motor vehicles including sensor processing, diagnostic and countermeasure implementation, serial communications, and control algorithms
- Design and implementation of automotive functional safety processes and software design consistent with ISO-26262 (Functional Safety for Road Vehicle Standard)
- Development of software requirements management, software architecture specification, model-based software design, and ASPICE (Automotive Software Process Improvement Capability dEtermination)

Professional Experience and Qualifications

- Product Engineer, Controlled Suspensions, Delco Products (1987 – 1989)
- Graduate Student (GM Fellowship) College of Engineering, The Ohio State University (1989 – 1991)
- Algorithm Engineer, Chassis/Suspension Integration, Chassis Systems Center (1991 – 1993)
- Application Engineer, Stability Control, Delphi Energy & Chassis (1993 – 2000)
- Algorithm Engineer, Stability Control Sensors, Delphi Energy & Chassis (2000 – 2003)
- Brake Controls Software Architect, Delphi Energy & Chassis (2003 – 2004)
- Engineering Manager, Diagnostics and Serial Communications, Delphi Chassis (2004 – 2008)
- Engineering Manager, Software and Systems Group, Delphi Chassis / BWI (2008 – 2016)
- Principal Engineer, Carr Engineering, Inc. (2016 – Present)

Publications and Achievements

- Master's Thesis: A DSP Hybrid Simulator For Evaluating Anti-Lock Brake System Control Designs, The Ohio State University (1991)
- Technical Publication: Survey of Software Failsafe Techniques for Safety Critical Automotive Applications, SAE International (2005)
- Technical Publication: Application of Robust Engineering Methods to Improve ECU Software Testing, SAE International (2006)
- Technical Presentation: Evolving OEM / Supplier Relationships Relative to System Design Satisfying ISO-26262, Car Training Institute (2012)
- Technical Presentation: Application of ISO-26262 "Confidence In Use Criteria" Toward ECU Software Development Tool Workflow, dSPACE Technical Conference (2013)
- Technical Presentation: The Next Frontier: Investigating The Alleged Vehicle "Software" Failure Claim, ABA Emerging Issues In Motor Vehicle Product Liability Litigation (2016)
- Technical Presentation: ISO 26262 Part 8: Supporting Processes, IQPC USA ISO 26262 Conference, (2017)
- Instructor SAE Course C1704: ADAS Application – Automatic Emergency Braking (2017)
- Competition Report Judge Formula SAE Collegiate Failure Mode Effects Analysis Exercise (2019 – Present)
- Recipient of seven US Patent Awards
- Recipient of GM President's Council Award: Automotive Chassis Control (1996)
- Recipient of two GM Boss Kettering Awards: Automotive Chassis Control – Integrated Chassis (1996) and Unified Brake and Suspension Control, Suspension & Steering (2000)

Technical Committees / Industry Affiliations

- SAE International – Member
- US Technical Advisory Group to ISO TC22/SC3/WG16 Functional Safety Committee
- INCOSE (International Counsel on System Engineering)

Attachment D

Testimony Record for Eldon G. Leaphart

Case Name	Case #	Venue	Type	Date
Bernardino v Nissan	BC 493949	Superior Court of CA, County of Los Angeles – Central	Deposition	06/02/2017
Bernardino v Nissan	BC 493949	Superior Court of CA, County of Los Angeles – Central	Trial	07/13/2017
Slayen v Mercedes-Benz USA, LLC	BC 633726	Superior Court of CA, County of Los Angeles – Stanley Mosk Courthouse	Deposition	02/28/2018
Slayen v Mercedes-Benz USA, LLC	BC 633726	Superior Court of CA, County of Los Angeles – Stanley Mosk Courthouse	Trial	03/26/2018
Makhlouf v Nissan	CL15-3214-00	Circuit Court for the City of Virgina Beach	Deposition	07/13/2018
Pahan v Kia	2014 L 004163	Circuit Court of Cook County Illinois County Department	Deposition	09/06/2018
Pahan v Kia	2014 L 004163	Circuit Court of Cook County Illinois County Department	Trial	10/04/2018
Hill / Parks v Kia	4:16-cv-117	United States District Court Eastern District of Tennessee at Winchester	Deposition	04/24/2019
Bicknell v GM	50-2011 CA 003575 XXXX MB AA	Circuit Court of the Fifteenth Judicial Circuit in and for Palm Beach County Florida	Deposition	05/15/2019 06/18/2019
Stroud v Kia	Case No. BC705872	Superior Court of California, County of Los Angeles – Central	Deposition	12/30/19

Stroud v Kia	Case No. BC705872	Superior Court of California, County of Los Angeles – Central	Trial	02/05/20
Stroud v Kia	Case No. BC705872	Superior Court of California, County of Los Angeles – Central	Trial	02/03/20
In re Pacific Fertility Center	Case 3:18-cv-01586-JSC	United States District Court of Northern District of San Francisco Division	Deposition	11/18/20
Perez – Duran v. FCA	Case No. 2:19-cv-13510	United States District Court Eastern District of Michigan Southern Division	Deposition	01/15/21
Sharpe v. Hyundai	Case No. cv-2020-900080	Circuit Court of Dallas County, Alabama	Deposition	3/31/21